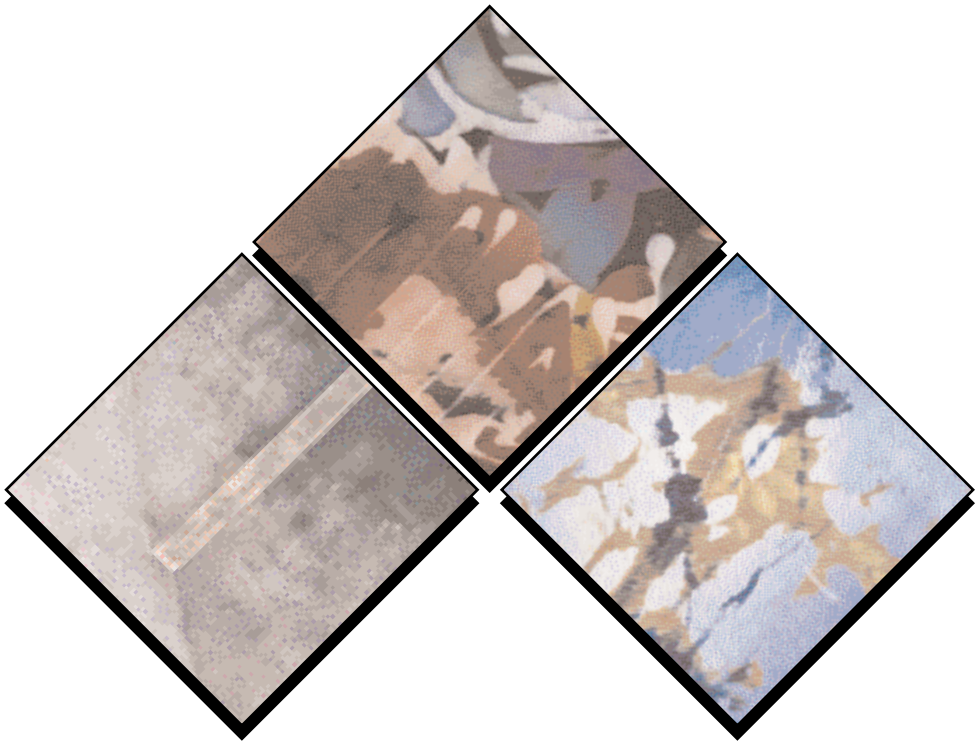
HEALTH NOTES



Quality Assurance

Communication and Public Education Committee

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HEALTH NOTES

VOLUME 1, NUMBER 6

Quality Assurance

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"The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures."

(Title 16 CCR, Section 1711)

An Opening Note:

The Board of Pharmacy's Perspective

Steve Litsey, Pharm.D., FASHP
President, June 1, 2001 – May 30, 2002
California State Board of Pharmacy

This edition of *Health Notes* will provide a starting point for learning about the application of quality assurance programs to pharmacy practice. The board has an absolute commitment to ensuring that patients receive quality pharmacists' care. The quality assurance requirement is the most important manifestation of that commitment since establishing mandatory patient consultation. The Board's goal for the quality assurance effort is to reduce the frequency of medication errors through the systematic study of those errors. Such study should provide pharmacists with the knowledge to improve pharmacy processes and systems to reduce the incidence of medication errors and to improve the overall quality of pharmacists' care provided to patients.

Background on the Development of Title 16 CCR, Section 1711

In July of 1999, the Board considered a regulation requiring pharmacies to implement quality assurance programs to reduce the incidence of medication errors. The Board undertook this effort for a number of reasons. First, medication errors were, and still are, the most common consumer complaint received by the Board. Second, Board members were concerned by the growing body of evidence published in the professional literature documenting the threat of medication errors to patient health. Third, the Board believed that systems and process analyses were the most effective means to reduce the frequency and severity of medication errors.

While considering the 1999 regulation, the Board received extensive comments from the industry and the profession. These comments focused on the potential threat of quality assurance records if a civil suit resulted from a medication error. In response, the Board removed the pending regulation from consideration and instead sponsored Senate Bill 1339 to require quality assurance programs and provide a statutory exemption from discovery for quality assurance records. At the same time, *To Err is Human* was published by the Institute of Medicine (IOM) and focused the attention of policymakers around the country on the need to reduce medication errors and improve the quality of medical care. This report made a compelling case for establishing broad-based quality improvement efforts focused on improving systems and processes. The successful implementation of quality improvement processes requires moving away from blaming individuals and moving towards improving systems to minimize future occurrences of medication errors.

On September 24, 2000, Governor Gray Davis signed Senate Bill 1339. This law requires pharmacies to establish quality assurance programs to reduce the frequency of medication errors, exempts documents generated by quality assurance programs from discovery, and requires the Board of Pharmacy to adopt a regulation specifying the requirements of a pharmacy quality assurance program.

On behalf of the Board of Pharmacy, I wish to thank Senator Liz Figueroa (D – Fremont) for authoring this groundbreaking legislation. Without her leadership and advocacy, the bill would not have been possible.

It is also worth noting that Senate Bill 1875 (Speier) also was enacted in 2000, in response to the concern about medication errors. This bill requires hospitals and surgical centers to develop medication error reduction plans and submit those plans to the Department of Health Services as a condition of licensure. Institutions that are subject to both Senate Bill 1875 and Senate Bill 1339 can comply with both laws with a single plan if that plan contains the elements required by the Board of Pharmacy's regulation.

Since Senate Bill 1339 was signed into law, the Board has been developing the regulation required to implement the quality assurance mandate established in Senate Bill 1339. The regulation has been the subject of extensive and vigorous debate and numerous modifications. That debate produced the essential elements of a pharmacy quality assurance program. It is important to keep in mind that the regulation represents the minimum required, not the most than can be done. The regulation provides each pharmacy considerable freedom to design and implement a quality assurance program that is adapted to its individual characteristics and needs. The Board trusts that pharmacies will use that freedom to innovate and find new methods for learning from medication errors.

Requirements of Title 16 CCR, Section 1711

Under Section 1711, pharmacies must develop a quality assurance program to study medication errors and learn from them how to prevent recurrence of the error. The regulation:

- Defines "medication error" as any variation from a prescription or drug order not corrected prior to furnishing the drug to the patient.
- Requires the quality assurance program to be documented in written policies and procedures.
- Requires the pharmacist to notify the patient and the prescriber of the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.
- Requires that the discoveries resulting from a quality assurance program be used to develop pharmacy systems and workflow processes to minimize the occurrence of medication errors.
- Requires that the investigation of each medication error commence as soon as is reasonably possible, but no later than two business days from the date the medication error is discovered.
- Requires that reviews of medication errors must include:
  a) Date, location, and participants in the review;
  b) Pertinent data and other information related to the medication error(s) being analyzed;
  c) Documentation of patient and prescriber notification;
  d) Findings and determinations resulting from the quality assurance review; and
  e) Recommended changes to pharmacy policy, procedure, systems, or processes, if any.

- Requires that records of the quality assurance review must be kept in the pharmacy for at least one year from the date the record was created.
- Requires that quality assurance records must be maintained by the pharmacy in an immediately retrievable form.
- Permits pharmacies to contract with qualified outside entities to develop and/or conduct their quality assurance program.

Enforcement

Section 1711 took effect January 14, 2002, and this regulation may require some pharmacies to implement significant changes in their operations.

Quality assurance programs will be reviewed during board inspections. The Board regards failure to implement quality assurance programs in compliance with this regulation as an extremely serious violation. The Board does not intend to use documents from a quality assurance program when investigating medication error complaints. However, when the investigation of a medication error has been completed, the inspector will review the pharmacy's quality assurance program and the pharmacy's assessment of specific errors. Failure to have a quality assurance program in place and/or failure to complete a quality assurance review in compliance with the regulation will result in enforcement action being taken.

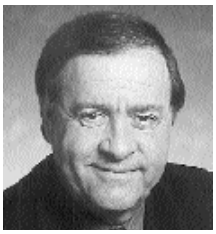
In closing, this edition of *Health Notes* is the product of the combined efforts of an extraordinary group of people. The contributing authors and faculty of the University of California, San Francisco School of Pharmacy all bring a wealth of knowledge and an abiding commitment to improving the quality of care provided by pharmacists. The Board is grateful for their efforts in making this publication possible. I hope you will find it as enlightening as I did.

EDUCATIONAL GOALS

This issue of *Health Notes* will provide information about:

- The incidence, cost, and impact of medication errors;
- SB 1339 and its accompanying regulation;
- Quality assurance principles and strategies applicable to pharmacy;
- How to help consumers take an active role in preventing medication errors.

It's Time for a New Model of Accountability



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Healthcare is struggling to come to terms with the role of accountability in the non-punitive, system-based approach to error reduction recommended in *To Err is Human*, the landmark 1999 report from the Institute of Medicine. Even when we seem to understand the system-based causes of errors, it's still hard to let individuals off the hook. We ask, "How can we hold individuals accountable for their actions without punishment?" Some have even suggested that a non-punitive approach to error reduction could lead to increased carelessness as people learn that they will not be punished for their mistakes. However, a non-punitive, system-based approach to error reduction does not diminish accountability; it redefines it and directs it in a much more productive manner.

Typically, when an error happens, all accountability falls on individuals at the sharp end of an error where the caregiver/patient interaction occurs. But accountability – not for zero errors, but for making patient safety job one – should be equally shared among all healthcare stakeholders. In part, Webster's defines "accountability" as an obligation to provide a satisfactory explanation, or to be the cause, driving force, or source. These definitions offer a glimpse at a more appropriate patient safety accountability model. In this model, accountability lies not in performing perfectly, but in identifying safety problems, implementing system-based solutions, and inspiring and embracing a culture of safety. Below are examples.

Individuals in the workforce should be held accountable for speaking out about patient safety issues, voluntarily reporting errors and hazardous situations, and sharing personal knowledge of what went wrong when an error occurs. On the other hand, healthcare leaders should be held equally accountable for making it safe and rewarding for the workforce to openly discuss errors and patient safety issues. Hopefully, the new California quality assurance regulation will help to facilitate regular management safety briefings with staff to learn about improvement needs, discuss strategic plans, and identify new potential sources of error. When the workforce recommends error prevention strategies, leaders must support them and provide the means necessary, within a reasonable timeframe, to implement technology and other system enhancements to improve efficiency and safety.

Leaders should be held accountable for understanding and addressing barriers to safe practice, such as distractions and unsafe workloads. Likewise, the workforce must be empowered to ask for help when needed and be willing to change practices to enhance safety and quality. Leaders should position patient safety as a priority in the organization's mission and engage the community and staff in proactive continuous quality improvement efforts, including an annual self-assessment of patient safety.[1]

The workforce should be held accountable for working together as a team, not as autonomous individuals. Finally, leaders and staff alike need to follow the safety literature continuously and offer visible support to their colleagues whom have been involved in errors.

This model of shared accountability spreads far beyond the walls of individual healthcare settings to encompass licensing, regulatory, and accrediting bodies; the federal government and public policy makers; the pharmaceutical industry; medical device and technology vendors; schools for medical and pharmacy training; professional associations; and even the public at large. These often-overlooked participants share equal accountability for doing their part to error-proof healthcare. For example, regulatory, accrediting, and licensing bodies should be held accountable for adopting standards related to error reduction recommendations that arise from expert analysis of adverse events and scientific research. Rather than experience the same mistakes happening again and again throughout the country, state pharmacy boards must work to identify the most common serious types of errors, work with licensees to develop prevention recommendations, and provide oversight to assure wide adoption at practice locations.

As an aside, I recently visited a practice site where, according to their internal error reports, Ortho-Cyclen® and Ortho-TriCyclen® were dispensed, in error, five times over the past two years. There were also errors involving confusion between Cortisporin® Ophthalmic and Otic Solutions – the same dispensing error I made myself over 25 years ago! Why does this happen? Here are some of the problems that may have contributed:

- Confusing drug names (and manufacturers' unwillingness to change to address problems that have been identified);
- Approval of look-alike packaging by the FDA;
- Overworked pharmacists and understaffed pharmacies;
- Workloads that exceed one's capability to provide safe care;
- Lack of dispensing technology (e.g., bar code, robotics, e-prescribing, image of original Rx on screen for refills, image on labels);
- Poor lighting in drug storage areas;
- Lack of safety alert to remind staff about potential errors (e.g., auxiliary labels, highlighting portions of the manufacturer's label, reminders on the container or shelf);
- Overwhelming array of alerts when processing orders in the computer system;
- Lack of an independent check of each other's work by at least two staff members;
- Inefficient processes for adjudicating prescriptions with third party payers;
- Lack of patient counseling;
- Patients who are unaware of their role in error prevention;
- Risk management program in the pharmacy fails to address errors that have been reported by other pharmacies through the USP-ISMP Medication Errors Reporting Program; and
- Inadequate quality improvement program.

Others are also accountable for reducing errors. Purchasers of healthcare should provide incentives and rewards for patient safety initiatives. Companies that produce medical devices, pharmaceutical products, healthcare computers and software, and other health-related products should be held accountable for pre-market evaluation and continuous improvement in the design of devices, products, and labels and packages. Educators should seek out patient safety information and use it in curriculum design. (By the end of 2001, no pharmacy school had a course on medical error prevention as part of its core curriculum and only a handful provided it as an elective course.) Professional organizations should support local and national voluntary reporting systems and disseminate important patient safety information to their members. Finally, the public should ask questions and stay informed about their care and ways to avoid errors.

Who can argue with the multidimensional nature of medical care? Isn't it time to accept a multidimensional, shared accountability model for patient safety? Organizational leaders and other stakeholders who simply hold the workforce accountable when an error happens are inappropriately delegating their own responsibility for patient safety. We must stop blaming and punishing those closest to an error, and instead accept a model of shared accountability to collectively translate our sincere concern for patient safety into effective system-based error solutions.

[1] For this purpose, NACDS, APhA and ISMP partnered to produce the ISMP Medication Safety Self Assessment Tool for Community Pharmacy (see www.ismp.org). This tools provides nearly 200 safe practice characteristics for you to assess and compare your practice with other pharmacies around the nation. It should be considered a must for every community pharmacy to complete this tool.

The Problem of Medication Errors

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***"First, do no harm."* Hippocrates**

"Health care is not as safe as it should be." This quote from the 1999 Institute of Medicine (IOM) report *To Err is Human: Building a Safer Health System*[1] summarizes the problem. *To Err is Human* broke the silence on medical errors and was the catalyst that focused national attention on patient safety. It was a call to understand the causes of medical errors and to search for solutions to reduce them. Still, errors continue to occur. What do we need to do to build a safer system for our patients?

Scope of the Problem

According to the IOM report, medical errors (preventable adverse events) cause as many as 44,000-98,000 deaths each year.[1] The authors concluded – in effect - that the health care system kills more people each year than anything other than heart disease, cancer, stroke, and pulmonary disorders, exceeding the mortality due to motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516).

Adverse drug events (ADEs) are the single most common type of adverse event in hospitalized patients,[2] occurring at a frequency of 2-7 ADEs per 100 admissions.[3,4] Each year, an estimated 770,000 hospital patients annually experience an ADE.[3] Adverse drug events have been reported to cost hospitals between $2.8 million and $4.2 billion annually, depending upon hospital size.[3,5] These figures represent direct hospital costs only, and not those associated with outpatient care or disability. When all costs are included, one estimate of the cost of drug-related misadventures in the United States was nearly $77 billion annually.[6]

Most adverse drug events are not life threatening or fatal.[4] Many are not preventable and reflect the intrinsic risks associated with drug therapy, such as when a life-threatening allergic reaction occurs in a patient not known to be allergic to the medication administered. However, when a patient receives an antibiotic to which he or she is known to be allergic, suffers an anaphylactic reaction and dies, a preventable ADE has occurred. One study found that almost one-third of ADEs were preventable.[4] Of the life-threatening and serious ADEs, 42 percent were preventable as compared to 18 percent of less serious ones.[4]

Medication errors occur much more frequently than ADEs, perhaps on the order of 100 times more often.[7] In one hospital study, investigators reported 5.3 errors per 100 orders, for a mean of 0.3 errors per patient day or 1.4 errors per admission.[7] Medication errors are not unique to hospitals. They also occur in other health care or practice settings, such as physicians' offices, pharmacies, and care delivered in the home. Unfortunately, there are very little data describing the extent of the problem outside of hospitals.

Fortunately, relatively few medication errors (about 1-2 percent) cause injury or an adverse drug event.[4] An additional 5 percent are "near misses," which means they would have caused harm or injury if they had reached the patient.

Why Do Errors Occur?

The health care system is complex, as is the medication use process within that system. Numerous discrete steps take place between the time a decision is reached to prescribe a drug and when a dose of that drug is administered to the patient. Practitioners representing more than one discipline participate in this process and can inadvertently introduce errors into it. Medication errors occur for various reasons, despite the good intentions of highly motivated and caring individuals.

Most medication errors are the result of faulty systems, not faulty people. Until recently, the prevalent culture in health care was one of blaming individuals. Poorly designed systems as an underlying cause of errors was not widely accepted.[8] To quote Michael Cohen of the Institute for Safe Medication Practices, a leading authority on medication errors, "The question of who was involved is of less importance than what went wrong, how, and why?"[9]

Statutory and Regulatory Requirements

Medication errors deserve the heightened attention we are now beginning to see. As a result, new initiatives to prevent or significantly reduce medication errors are now in place.

Legislation. The California State Legislature recently enacted two bills, SB 1875 and SB 1339.

- SB 1875 requires hospitals to develop and implement plans to reduce medication errors. Hospitals were required to submit their plans to the state Department of Health Services by January 1, 2002 and are required to implement them by January 1, 2005.
- SB 1339, the subject of this issue of *Health Notes*, requires all pharmacies to implement a quality assurance program to reduce medication errors.

The JCAHO Patient Safety Standard. The Joint Committee on the Accreditation of Healthcare Organizations (JCAHO) established a new safety standard for hospitals. It requires hospitals to:

- Designate one or more qualified individuals to manage an organization–wide patient safety program;
- Establish clear expectations for internal reporting of error information;
- Implement mechanisms to support staff members who have been involved in a sentinel event;
- Report annually to the governing body the actions that were taken to improve patient safety; and
- Implement a systematic assessment process that enables organizations to proactively identify points of risk in the medication use process.[10]

The Pharmacist's Responsibility

This goal of this issue of *Health Notes* is to share the tools and safety strategies that will assist you in creating a "culture of safety" in the delivery of medications. Such a culture begins with an awareness that the "fault" for a medication error is often the result of a system failure, rather than a failure of an individual. This issue will help you to better understand the principles of quality assurance and error reduction; share lessons learned from low-error systems outside of pharmacy; provide tools and strategies for identifying, reporting, and analyzing errors; and empower consumers to do their part to prevent errors.

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Building a Safer System:
Experience of Other Industries

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In U.S. hospitals, as many as 98,000 Americans die each year as a result of medical errors. This troubling statistic is one of the first statements from the Institute of Medicine Report, *To Err is Human*.[1] After the release of this report, several newspaper headlines equated these 98,000 annual deaths to a fully-loaded Boeing 747 crashing every working day, killing all those on board. Since our society would never tolerate such a terrible situation in the airline industry, why should it tolerate an error rate in the health care industry resulting in the same mortality?

Comparisons with the airline industry and others that demand safety systems are powerful and should motivate those of us within the health care industry to learn from them as we develop our own quality assurance programs. In reviewing the safety literature within these non-health care industries, there are three areas in which differences exist. They are the logic structure used to analyze errors, the methodology used to identify potential failures and their untoward effects, and the role of simulation in preventing errors. A description of each follows.

The Logic Structure Used to Analyze Errors

The logic structure that has been used predominantly within the health care setting is *deductive logic*. The basic structure of deductive logic is to start with the consequences of an error and work backwards in order to draw an inference as to the possible causes.[2] For example, a physician calls the dispensing pharmacist to inform the pharmacist that her patient reported his latest prescription was dispensed erroneously. If this error occurred within the hospital, a multi-disciplinary task group would be established to identify the causes and possible solutions for preventing future occurrences. The task group would probably use a methodology called *root cause analysis (RCA)* to conduct the evaluation.

The physician then states that the prescription was mislabeled. Instead of the prescribed "take one tablet before each meal," the label reads, "take two tablets before each meal." In a root cause analysis, the sequence of events associated with the incident is identified and the root contributory factors are distilled from this examination. In our example of the mislabeled prescription, there may be many root contributory factors. For each factor, a corresponding action plan would then be identified.

Conversely, *inductive logic* starts with the causes or contributory factors in order to identify the possible consequences that may stem from each of them. Inductive logic is a *priori* (i.e., from cause to effect) and as such requires understanding of some key concepts. These are frequency, severity, and risk.

- Frequency is the probability that an undesired outcome will occur per a specified unit of time.
- Severity is the ultimate detriment that will result from the undesired outcome or event.
- Risk is the relationship between the severity of the consequence that results from an error and the frequency of that specific error.

Analyzing a system a *priori*, such as a medication use system, has the obvious advantage of identifying potential sources of error before an error occurs. The basic structure of inductive logic starts with the examination of a potential causative factor and then assessment of the consequences that can stem from it.[2] Using inductive logic optimizes the reliability and the safety of the stated system. Returning to our mislabeled prescription example, the possibility of getting a call from a physician describing an error would be lessened. The reason would be that mislabeling would have been identified as a logical consequence stemming from one or more causative factors, such as illegibility of physician's handwriting or dispensing prescriptions during peak demand periods. Actions that will prevent causative factors contributing to a mislabeled prescription would be identified and designed into a "fail safe" system in advance of an error.

Methodology to Identify System Failures or Potential Failures

As described previously, root cause analysis uses deductive logic. A methodology containing the inductive logic structure is called *failure mode and effects analysis (FMEA)*. It is used in the military and has also been frequently used in the airline and the aerospace industries (e.g., National Aeronautical and Space Agency, NASA). This methodology provides an organized structure for identifying individual elements or operations within a system that will render the system vulnerable to failure. It identifies failure consequences and assists with an array of recommendations to mitigate each identified failure point. The methodology is generally used to identify points of failure in mechanical systems and not in systems where human beings are the main components within the system. However, the health care system is a complex mixture of both mechanical and non-mechanical elements, in which FMEA may play an important role at the nexus.

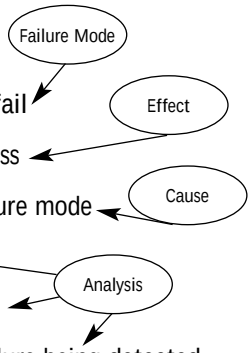
The FMEA process starts with three basic questions after the system under evaluation has been broken down into its various components or subsystems. These questions are:

1. Will a failure of the system or a subsystem result in an undesirable event?
2. For each of the systems or subsystems, what are the potential failure modes?
3. For each of the potential failure modes, what are the undesirable effects?

A FMEA worksheet is generally developed to document the evaluation, as well as to track and monitor the actions identified that address each failure mode. A typical worksheet would contain the following key elements: the system or subsystem, potential effect(s) of failure, severity of effect(s), potential cause(s) of failure, probability of failure, design controls to prevent failure, likelihood of detection, risk priority, recommended action and responsibility, and target date for completion.

12 Steps in Failure Mode & Effect Analysis (FMEA)

1. Form a mulitdisciplinary group
2. Understand the process
3. Brainstorm ways the process can fail
4. List effects of failure on the process
5. List root causes that generate failure mode
6. Estimate likelihood of failure
7. Estimate severity of failure affect
8. Estimate the probability of the failure being detected
9. Compute the criticality index
10. Brainstorm activities to reduce criticality index
11. Take action
12. Follow up



OCCURRENCE RANKING

Likelihood	Definition	Probability	Rank
Remote	no known occurrence	1:10,000	1
Low	possible but no known data	1:5,000	2,3,4
Moderate	documented, but infrequent	1:200	5,6
High	documented and frequent	1:100-1:50	7,8

DETECTION RANKING

Likelihood	Definition	Probability (10)	Rank
Very high	system will always detect error		1
High	likely to be detected before it reaches patient	7	2,3
Moderate	moderate likelihood of detection	4,5	4,5,6
Low	low likelihood of detection	1,2	7,8
Remote	detection not possible any time, any system	0	9

Figure 1.
The systematic assessment of a process or product that enables one to determine the location and mechanism of potential failures

The FMEA worksheet may look like the following, where the top row illustrates an examination of the braking system within the automotive industry. The second row illustrates a medication dispensing subsystem using our mislabeled medication error.

System/ Subsystem	Potential Failure Mode	Potential Effect(s) of Failure	Severity of Effect	Potential Cause(s) of Failure	Probability of Failure
Braking Subsystem	Loss of Braking fluid	Cannot stop when needed	8	Break in fluid line	5
Transcribe	Misread MD order	Patient will receive wrong drug	10	Use of non-standard abbr.	3

For each identified potential effect of failure, the evaluator or evaluation team will assign a severity rating (1-10 with 10 being very severe). Similarly, a probability rating is given to each potential cause of failure (1-10 with 10 being very high).

The worksheet continues with identification of the design controls that are intended to prevent or mitigate the failure, as follows:

Current Design Controls	Likelihood of Detection	Risk Priority Number	Recommended Action(s)	Responsibility and Target Completion Date
Brake warning light	1	40	preventive maintenance of all brake fluid lines after every x miles	
RN double checks	2	60	Education on standard abbreviation	

A detection rating is given to each current design control (1-10 with 10 being highly undetectable). A risk priority number is then calculated for each potential failure mode. The risk priority number is the product of the severity rating multiplied by the probability rating and multiplied again by the detection rating. The potential failure mode with the highest risk priority number will have the highest potential to fail with severe consequences.

Applying this methodology to the pharmacy dispensing system would result in a FMEA worksheet as follows:

System/ Subsystem	Potential Failure Mode	Potential Effect(s) of Failure	Severity of Effect	Potential Cause(s) of Failure	Probability of Failure
Rx Dispensing	mislabeled dosage on prescription	Pt. will receive the wrong dose	10	Constant interruption via the phone	5
				Cannot read MD handwriting	5

Current Design Controls	Likelihood of Detection	Risk Priority Number	Recommended Action(s)	Responsibility and Target Completion Date
Double-check label against Rx	3	150	1. Reduce interruption by instituting a call triage process 2. Read the label out loud by a second person as one verifies Rx	
Call MD	1	50	Refuse to dispense and call MD for clarification	

Once the recommended actions are identified, they are accepted and implemented. If the recommendations are robust, the detection and/or the probability of failure ratings may be lowered. For example, if the two stated recommendations are successful in preventing mislabeling errors, the detection rating may be dropped to a lower number than 3 and the same for the probability rating. The lowering of ratings are not done unilaterally but are done under consensus using various identification methods, such as literature support, historical antecedents, modified Delphi[i] and others.

Advantages

The FMEA methodology adds another perspective to error analysis and management. Its primary advantages are that it enables:

- Prioritization of system weaknesses requiring attention;
- Identification and development of redundancies within a system or subsystem;
- Development of design change to increase system reliability;
- Development of better monitoring or detection systems; and
- Reduction or elimination of service and/or environmental stresses, such as constant computer system outages.

Limitations

Obtaining, interpreting, and applying severity, probability of failure, and detection ratings can be difficult and tedious. This is one of the limitations associated with FMEA. Three other major limitations to the FMEA methodology are as follows:

- It only examines individual faults of system elements; the combined effects of simultaneous failures are not considered;

[i] *A method to reach consensus by polling experts and collecting data in a structured manner.*

- It takes time to complete a full analysis, especially for complex systems; and
- It is not geared to identify human frailties.[3]

Role of Simulation in Preventing Errors

Complex systems, like the medication delivery system, have gaps between processes, subsystems, people, and information. In many analyses of mistakes made in the medication delivery systems, gaps (especially information gaps) are identified as contributing factors to the error. For example, our mislabeling error can be categorized as an informational gap error. If the dispensing pharmacist had been aware of the patient's diagnosis, would the mislabeling error have been caught?

In the military and other industries (e.g., aviation), units use simulation as one of the bridges to span the gaps in complex systems. Simulation games can be useful learning tools, because individuals learn to work with other team members in order to accomplish a stated mission. As a result of being tested together within the simulation, team members develop a strong teamwork ethic and *esprit de corps*.

Working under simulated, but realistic, conditions pushes the team to "storm" together before they can "perform."[ii] Conflicts among and between team members become real, but highly useful to fostering and strengthening communication channels before the team is actually deployed. Conflicts arise that deal with informational gaps, forcing the team to work through these situations. A wonderful byproduct of "storming" is the establishment of a new culture among the team members. Even though there may be an established hierarchical structure within the team, as in the military, the constant testing under simulated conditions allows junior members to speak up when a senior member is about to make a grave error.

This latter point is very important in the health care industry, because there is a definite hierarchy. Physicians generally dictate the action (treatment) plans for the patients. If the physician was about to make a grave error that could result in harm to the patient, would we be able to speak up? If not, perhaps, simulated scenarios among health care team members may be helpful in developing the ability to speak up to prevent harm. Constant simulated play by a health care team can result in bridging gaps created by the hierarchical structure.

The key advantage of simulation is that it develops tacit knowledge among team members. There is instant feedback on how an individual and the team performed. The saying that "we should learn from our mistakes" is the norm in simulated games. During these simulated situations, unforeseen scenarios are created for the individual member and team to negotiate. Errors are constructively criticized and changes are made. Correct actions are reinforced.

In today's health care industry, there is a tremendous shortage in our labor force and it is working in a stressful, ever-changing environment. Simulation is very important in these situations and would help protect patient safety. Would you fly in an airplane knowing that the pilot had never before flown with the aircrew assigned to your flight?

Conclusion

In health care, the obvious adverse consequences that should be avoided in our patients are injury, iatrogenic illness, and death. Other adverse consequences could be loss of reputation, loss of money, and medical-legal lawsuits. In the final analysis, the approach used by other industries to reduce errors differs significantly from that used in health care. The health care industry, and more specifically the pharmacy profession, has much to learn from them.

[ii] *Refers to the process of teams coming together as originally described by Henry Mintzberg: forming, storming, norming, performing.*

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Tools for the Reflective Practitioner:

Using Self-Monitoring, Personal Feedback and Goal Setting to Reduce Error

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In a recent letter that I received, a pharmacist remarked, "Part of the reason for errors is that filling prescriptions is like an assembly line operation. It seems like a never-ending task. We get so busy that we often don't have time to think. Pharmacists become like robots with our brains on the back burner!"

Pharmacists are not alone. Researchers estimate that 70-80 percent of our waking life uses the mental equivalent of an automatic pilot.[1,2] This is particularly true of familiar tasks such as driving cars, exercising, and performing the repetitive and routine parts of our jobs. Our conscious awareness drops and largely automatic modes of thinking and behaving take over. Harvard University psychologist, Ellen Langer, labels this mental state *mindless thinking* and contrasts it with what she calls *mindful* or conscious and reflective thinking.[3] Each mode of thinking has its advantages and disadvantages.

On the positive side, our ability to engage our "autopilots" saves time and energy for reflective thinking on interesting and challenging tasks. Thus, when asked whether a combination of three medications could have side effects, a pharmacist switches into a mindful mode of thinking. Since most of the dispensing process largely occurs automatically, additional time is available for a thoughtful answer. Reflective thinking and processing of information reduces accident and error rates, lessens anxiety and stress, and gives people a sense that they have more control in their lives.[4,5]

On the negative side, mindless thinking creates a mental fog with less conscious attention paid to the task at hand. Rules and procedures may not be used properly, and normal checkpoints may not be thoroughly conducted. In a pharmacy, these short cuts can translate into a variety of mistakes. Familiar examples include the misspelling of patient or physician names during data entry, placing incorrect directions on a label, selecting the wrong drug or strength, rushing the final verification of a prescription, or failing to counsel patients on new prescriptions.

Clearly, devoting additional conscious attention to tasks, especially during normal checkpoints, will be helpful. Also, periodic analysis of the strengths and weaknesses associated with how tasks are conducted and the outcomes of any changes can improve the safety and quality of work. The new quality assurance regulation to reduce medication errors (Title 16 CCR, Section 1711) encourages the analysis of mistakes and the development of remedies.[6] It is *reflective practitioner-friendly* legislation. It provides permission, protection, and an incentive for pharmacists to learn from their mistakes.

There are two sides to most things in life and the new quality assurance law in California is no exception. While it will undoubtedly yield dividends in improving patient safety, *it may inadvertently limit what can be learned and achieved*. The problem lies in how a medication error is defined in the new regulation. Specifically excluded from the definition of an error is "any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law."[6] This definition of a medication error is reasonable, but it may limit the focus of analysis to *those adverse outcomes that account for a minority of the mistakes that pharmacists make*.

In contrast, errors made and corrected in the process of achieving a correct outcome, or "near misses," provide extremely valuable information about conditions producing errors. I label such mistakes *process errors*. Analyzing process errors produces information about the causes of error and suggests how they might be managed. These lessons are less likely to emerge from a study of outright medication errors alone.

Important Characteristics of Process Errors

Process Errors Are "Real-Time" Errors

Currently, several strategies are used to analyze the cause of errors. But they are initiated either after an error has occurred (e.g., root cause analysis and pharmacy incident report analysis) or in advance of a potential problem. The latter strategy is used to assess potential risk in new procedures or changes in drug use and distribution systems (e.g., failure mode and effects analysis). A drawback of such techniques is that some dispensing errors are not easily reconstructed after the fact and conditions likely to produce errors that are not totally predictable beforehand. For example, consider what normally occurs when patients discover errors. Such mistakes are often called to the pharmacist's attention hours or even days after the event happened. Memories for events fade with time, facts are remembered and assembled selectively, and emotions associated with a medication error can interfere with an accurate reconstruction of what actually happened.[7,8] When asked about the causes of errors on incident reports or in focus groups, pharmacists typically respond with such statements as, "I was busy," "I was distracted by a customer's question," "It happened out of the blue like a bolt of lightning," or "Must have been a bad roll of the dice."[9] These and similar statements do not help to identify underlying causes.

In contrast, because process errors are monitored in *real time*, additional sensitivity to psychosocial factors and the nuances of environmental, workflow, and other factors can be obtained. Recent cases of serious errors suggest that mental distraction, following rigid rules, and emotional states affected the error, but were largely ignored in traditional analyses of the problems. The medication errors occurred when a pharmacist was preoccupied with the recent death of a spouse, when a nurse invoked a cultural injunction to "not challenge authority and thus I assumed the doctor knew what he was doing," and while a pharmacist was worried about her children on a camping trip as a severe storm approached.[9,10,11] Psychosocial factors can lead to specific interventions. In the cases mentioned here, a company bereavement leave policy should be in place; assertiveness training for employees in managing authority would teach valuable skills; and a culture

encouraging workers to ask colleagues to help check their work when emotional levels are high could have prevented the errors. Such lessons learned can be combined with traditional root cause and failure-mode analyses to provide a comprehensive picture of the causes of medication errors.

Increases in Process Errors are Precursors to Medication Errors

There are many more process errors than outright mistakes. As they increase, so do the chances of a mistake getting past normal verification checkpoints.[12] On average, for every six process errors, one mistake will find its way into the "will-call bins" waiting to be picked up or directly into the hands of patients. This ratio of process errors to mistakes that get past normal verification processes is remarkably stable and has been observed in retail pharmacy field-sites, an outpatient hospital pharmacy study,[13] and in a pharmacy simulation laboratory.[14]

Process Errors are Like a Double-Edged Sword

They are good, because a mistake was caught and corrected. Unfortunately, process errors are bad as well, because they signal that mental processes drifted into an error mode. Too many of them are a sign that the *fog of mindless thinking is emerging*. Pharmacy personnel should take precautions. *A rule of thumb is that six or more processes errors per hour should be treated as an alarm.*[i] This lesson is easily applied. One pharmacy manager told me that she watches herself and her staff carefully. "When I notice them fumbling about and making too many corrections, I require a break or a shift in their tasks and require additional checks of their work." A pharmacist remarked, "When they increase, I take a break or do a non-dispensing task for awhile." Such actions lessen the chances of patients receiving incorrect prescriptions.

Capturing Process Errors

Periodic Self-Monitoring of Performance

In a study of 84 pharmacists in 36 retail pharmacy field-sites, pharmacists monitored themselves for 9 hours a week over a 4-week period, equally dividing their time between early, middle, and late parts of their shifts.[12,16] The form used to document critical events is shown in Figure 1. It was part of a 4 x 6 inch booklet the pharmacists carried with them or kept close by in the workspace. Multiple copies of the form were available in the booklet to cover the periods of time on the shift they would spend monitoring performance. The pharmacists placed a hatch mark or check in the proper space on the form whenever a critical event occurred (e.g., a change in data entry or final verification). Everyone was instructed to make an entry only when it was safe to do so. The monitoring packet also included forms for recording emotional states and perceptions of subjective workload. The latter included ratings of perceptions of mental demand, time demand, physical demand, concern for doing well, effort required, and frustration with their work.[ii]

This form can be used as shown, or adapted to reflect aspects of particular pharmacy environments or any specific

SELF-MONITORING OF PROCESS ERRORS

Day ____ Part of Shift (Early) (Middle) (Late)

Time of day you began ____ ended ____

Scripts you helped to fill during this time ____

Correcting information to patient on telephone

Correcting script information when copying from a telephone call or FAX transmission

Date-entry changes

Product selection changes

Count & pour changes

Corrections during normal checkpoints

Counseling patient or answering patient questions

Correcting script after it was placed in "will-call"

Figure 1: Form used to monitor process errors

[i] *Author's opinion and not necessarily that of the California State Board of Pharmacy.*

[ii] *The National Aeronautical and Space Administration – Task Load Index was used. This tool allows people to judge the amount of subjective workload they are experiencing during different parts of a task or during various times of the day. Judgments are made of a scale that ranges from 1 – 100 where one indicates a low level of task tension and 100 a very high level of task tension. Scores on each of the subscales are also combined to yield an overall composite of subjective workload. It is one of the most highly reliable measures of subjective workload available.*

information needs the pharmacy might have. For example, the categories could be modified to include look-alike or sound-alike product confusion, number of times the work of a technician was corrected, process errors associated with working on third-party insurance requirements, specific data-entry mistakes made, or environmental or workflow conditions present. Also, the amount of time monitored could vary based upon individual circumstances (e.g., three times a week every month, one day a week, or for several hours after an increase in process or other errors are noticed). Finally, monitoring forms could be used to periodically check 10 percent of the prescriptions in will-call bins against the original prescription for mistakes. In the latter case, monitoring for a wrong prescription in the bag, incorrect directions and other label information, incorrect count/amount, wrong strength, and wrong drug could be examined.

Process error monitoring is best used for personal development. As such, individuals or teams might conduct such analyses. The goal is to provide information for personal use and professional development. There is no need to archive any records gathered since the objective is to use what is learned immediately.

Outcomes of Monitoring

Table 1. summarizes several patterns in process errors that were observed in the study of 84 pharmacists across 36 retail field sites.

Percentage of Process Errors **	Percentage of Process Errors **
Overall (8.4 percent)	Ratings of Pharmacy Lighting
	Rated Adequate (11.8 percent)
Scripts Worked on Per Shift	Rated Inadequate (8.5 percent)
Low [40-105] (11.2 percent)	
Medium [106-192] (7.9 percent)	Percent Reduction due to
High [193-327] (6.1 percent)	Eye-level script-holder (35 percent)
	Each independent check
Distribution in Monitoring Form	after final verification (95 percent)
Patient on Telephone (4.2 percent)	
Copying Information (8.6 percent)	Subjective Workload
Data Entry (41.3 percent)	Low Error- 6.6 percent- (60 of 100 pts)
Product Selection (12.5 percent)	High Error -10.2 percent- (40 of 100 pts)
Count & Pour (14.4 percent)	
Normal Checkpoints (14.2 percent)	Supervisory Effectiveness
Counseling Patients (2.6 percent)	Rated Effective (<4.8 percent)
After Prescription Placed in Will-Call (2.2percent)	Rated Ineffective (>11.6 percent)
High to Low Vol (7.1 percent to 10.2 percent)	
	Workload **&** Error Change***
	High to Low Vol (7.1 percent to 10.2 percent)

*Table 1. Summary of Findings from Monitoring Process Errors. **

* *Adapted from references 16 – 18*

** *All percentages based upon the number of process errors observed divided by the number of prescriptions filled.*

*** *Low workload was (< 15 prescriptions per hour). High was (> 25 prescriptions per hour).*

Learning from Process Errors

Using Patterns in Process Errors to Design Interventions

While interesting in their own right, analysis of the outcomes shown in Table 1. led to development of the following strategies to improve patient safety. [12,16-18]

Data entry: Use scanning technology. Keep information at eye level when typing it into a computer data base. Use copy or monitor-stands to hold a prescription at a comfortable visual angle to decrease errors.

Verification: Use independent double checks of work completed. Control interruptions of people when verifying work. Use adjustable task lights and magnification devices to increase visual acuity during verification.

Patient Counseling: Take more time to counsel patients and use a "show and tell" technique when dispensing new prescriptions, as follows. Open the vial of medication when counseling the patient, shake one tablet or capsule of the medication into the cap of the vial, and tell patients the name of the drug and the directions for its use. For refills, ask "is this what you expected to get?" This forces the patient or caregiver to consciously reflect on what was received, to ask questions, or to find out what was received the last time.

Negative perceptions of lighting: Take complaints about light levels or equipment seriously and take immediate steps to improve them. Perceptions that pharmacy lighting was adequate were associated with fewer process errors. This mirrors what happens when illumination levels were actually increased in research studies.

Workload Shifts: Work on non-dispensing tasks or review work completed in order to "get back into the task" or warm-up after a break or lull in workflow. Shifts from conditions of high to low workload and working under conditions of low workload led to more process errors. One reason is that low workload leads to boredom and people begin to think about non-task related items. Also, dramatic shifts from high to low workload disrupt normal work-rhythms. In both cases, engagement with the task drops.

Active attempts to regulate workload should be initiated. Consider prioritizing work to be completed by using different colored baskets and computer guided work priority systems to separate prescriptions needing immediate attention from those that can be filled later. Or, if possible, have some filled centrally when overloads occur, and always ask patients in outpatient and community pharmacy settings to state when they need to have their prescription ready.

Supervision: Use effective supervision skills. Ineffective supervision was seen as overly controlling, which did not allow people appropriate autonomy on the job. It led to job dissatisfaction, stress, and mental distractions that interfered with accurate and productive performance.[20] Similar finding have also been observed among nurse-pharmacist-physician teams.[21] Under such conditions people intercept and report fewer errors.

The most helpful supervisors have the following attributes:

- Set clear goals and directions for the work that people do;
- Help establish a climate for excellence and professionalism;
- Provide clear expectations;
- Delegate appropriately the freedom to do a job;
- Seek the opinions of those affected before making decisions;
- Insure that the reasons why something is done are clearly stated;
- Provide sufficient answers to questions;
- Adjust supervisory style to accommodate differences among people; and
- Make people feel involved and important.

Use Feedback from Self-Monitoring to Set Performance Goals

After the first two weeks of the project, pharmacists working in 12 of the field-sites were asked to calculate the percentage of process errors they observed before sending their booklets to the research team. Based upon a chart showing them the average percentage of process errors that all pharmacists in the study made, they set a performance goal for the following two weeks. Their choices were:

- "I am satisfied and will maintain my current level of work performance."
- "I am dissatisfied and want to improve my ability to detect mistakes."

The outcomes of this intervention are shown in Figure 2.

The data clearly show that attending to feedback and setting goals were helpful. Compared to a control group of participants working in 12 stores where no feedback was provided, those who set a goal to maintain their performance detected 22 percent more process errors. On the other hand, those who set a personal goal to improve what they did increased their detection of process errors by 103 percent. *They became more mindful of their actions on the job and were better able to notice problems*. While comparing one's performance to others is useful, establishing personal improvement goals based on monitoring behavior also should have beneficial effects.

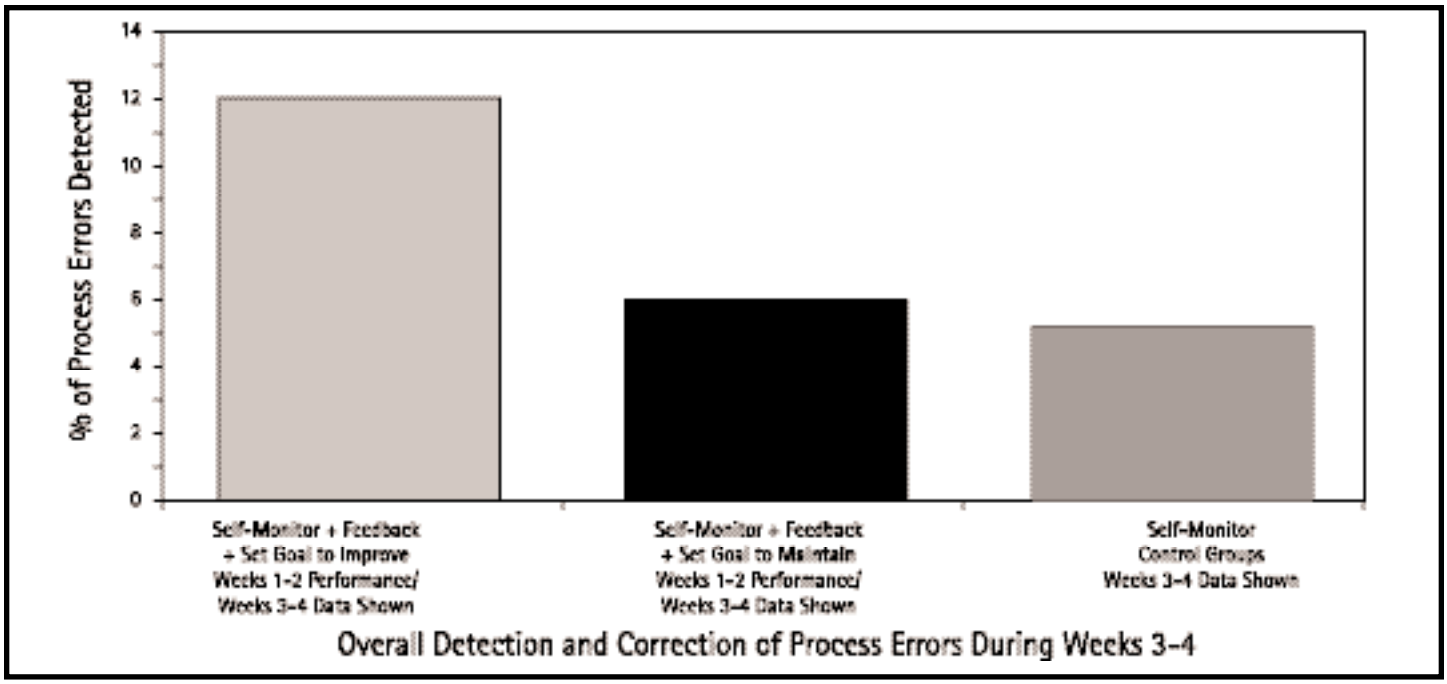

Figure 2: Effects of performance feedback provided after self-monitoring process errors during the weeks 1-2 of the protocol. Participants were asked to set a goal of either maintaining or improving process error detection during weeks 3-4. Chart shows performance improvement during weeks 3-4 compared to a control group than did not receive feedback or set goals.

Conclusion

Taking more time to become mindful or to consciously focus on work in process or completed benefits patient safety. This entails increasing the time spent as a reflective practitioner and using processes that actively facilitate such thinking. A general sensitivity to the interplay between cognitive and other psychosocial factors and pharmacy practices should be a part of such analyses.

More detailed information on how to accomplish such goals is available in several recent publications for pharmacy personnel.[iii]

[iii]*There are innovative self-study materials that cover the practical applications of the interplay between cognitive, psychosocial factors and traditional pharmacy practices in reducing error, risk management, and promoting patient safety. Ten self-study modules on the latter topics were supported from an unrestricted educational grant from the McKesson Foundation and will be available to pharmacy personnel worldwide beginning in July 2002. Interested readers should view the non-commercial website (www.pharmsafety.net) where the modules can be downloaded free of charge. CE credit is available for US and Canadian Pharmacists. The development team included Anthony Grasha, Ph.D., David Brushwood, R.Ph., J.D., Michael O'Neill, R.Ph., and Kraig Schell, Ph.D.*

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Documenting Medication Errors: **Tools for Performance Improvement**

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The United States Pharmacopeia (USP) is a practitioner-based organization that sets standards for the identity, strength, quality, purity, packaging, and labeling of therapeutic products. USP's standards-setting body is the Council of Experts, formerly the Committee of Revision. This committee maintains and continuously revises the *United States Pharmacopeia and National Formulary (USP-NF)* and the *USP-DI®*. As a non-profit corporation working in the public interest, USP also operates several public health programs that further help to assure that practitioners and patients/consumers have access to high quality therapeutic products and that they are used wisely. Patient Safety is one of these programs.

USP's interest in patient safety began with the understanding that names and labels of therapeutic products can either reduce or enhance the likelihood of a medication error. Reports from practitioners were and continue to be critical to this understanding. To facilitate practitioner reporting, USP now operates two complementary error-reporting programs. These are the USP Medication Errors Reporting (MER) Program, which operates in cooperation with the Institute for Safe Medication Practices (ISMP), and MedMARx℠. Both yield information that has been highly useful to USP's standards-setting activities, to practitioners and patients or consumers, and to regulatory bodies such as the Food and Drug Administration (FDA). USP's Council of Experts has two expert committees that focus specifically on information from the MER Program and MedMARx. These are the Labeling and Nomenclature Expert Committee and the Safe Medication Use Expert Committee. While both programs collect essential data on medication errors submitted by health care practitioners, there are some important differences.

The Medication Errors Reporting (MER) Program

The MER Program allows health care professionals from any practice site (e.g., retail pharmacy, hospital, clinic, nursing home) to spontaneously report both actual and potential medication errors in a confidential and, if desired, anonymous manner (Figure 1). Reports can be submitted by mail, fax, phone, or online (www.usp.org) and are compiled into a national database. USP reviews each report for health hazards and forwards all information to the ISMP, the FDA, and the product manufacturer. The MER database is not accessible to individual practitioners. However, pertinent findings are disseminated to practitioners primarily through the USP Quality Review and Practitioner's Reporting News releases, as well as through ISMP newsletters.

By sharing experiences through the MER program, pharmacists contribute to the collective learning about the types and causes of medication errors. This understanding in turn leads to recommendations and actions to prevent recurrence. Reports collected through the MER Program are reviewed by USP's Safe Medication Use Expert Committee, which can recommend changes or additions to USP standards. USP's Labeling and Nomenclature Committee can also consider name and labeling changes. USP can also implement error-prevention strategies by working collaboratively with partners such as ISMP, FDA, and the United States Adopted Names Council. Depending upon the nature of the medication error, MER Program reports become the basis for ongoing discussions between the FDA and manufacturers, and if warranted, regulatory action. The reported concerns of practitioners have prompted USP, FDA, and various drug manufacturers to institute numerous changes and improvements to drug products and have contributed to safer medication prescribing and use. Over the last five years, USP has received about 5,000 reports to the MER Program, most of which were submitted by pharmacists.

The following case study, abstracted from an MER report, illustrates how reporting identifies issues and concerns that need to be brought to the attention of product manufacturers.

> *A female patient was prescribed a topical anesthetic cream with three refills. The prescription stated only that the cream should be applied before her scheduled laser procedures. Fearful of pain, the patient obtained all allowable refills (having the prescription refilled approximately every 7-10 days) and applied all the medication to the skin before the first procedure. The patient experienced a drug overdose that required intubation. She suffered an extended unconscious period and spent several days in the hospital. At discharge, the patient was put on diltiazem and had to use a walker.*

This example demonstrates how patients can be put in a precarious position if the product's packaging or the prescription label does not contain specific dosing instructions. California's law now requires pharmacies to implement a process for documenting and analyzing medication errors. Pharmacists can use the MER form as one way to document and trend error incidents. Moreover, review of published news items from the MER database should help pharmacists identify potential error-prone areas and analyze causes for error.

The MedMARx Program

Based on the experiences from the MER program, USP developed MedMARx, an Internet-accessible, performance improvement tool designed for hospitals and health systems.[1] California's SB 1875 requires all general acute care hospitals, clinics, and specialty hospitals to develop effective reporting mechanisms to ensure that medication errors are reviewed by a multidisciplinary group. Hospitals using MedMARx are able to anonymously collect, track, and analyze medication errors in a standardized format. Subscribing hospitals can access the MedMARx database program, which enables them to compare their own medication error data with other hos-

pitals on a national level. The database also provides hospitals with a powerful tool to concurrently and proactively assess error-prone areas, identify opportunities for systems improvements, and apply risk prevention strategies by taking steps to "error proof" their hospital based on the unfortunate experiences of others.

The MedMARx program uses a medication severity index created by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) as the basis for categorizing errors.[2] (Figure 2) USP provides secretarial support to NCC MERP, which is a working coalition of seventeen organizations that promotes the reporting, understanding, and prevention of medication errors. The NCC MERP medication error category index consists of nine categories, ranging in severity from A (the potential for error existed) to I (the error resulted in patient death). Categories also differ on the basis of whether the error reached the patient and if the error caused temporary or permanent harm.

In addition to the severity index, NCC MERP has developed other related error nomenclature, including the following definition for a "medication error:"[i]

> *A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.*

Standardized definitions, indexes, and nomenclature help pharmacists to more uniformly collect, track, and compare medication error data. MedMARx allows the user to enter detailed information related to a medication error incident. This includes the error category; date, time, and type of error; possible cause(s); contributing factors (e.g., workload, staffing shortages); location of error; product(s) involved; general patient data (e.g., age, gender); and type of staff involved.

MedMARx is designed for use as a multidisciplinary tool to capture medication errors in any hospital area. It allows users to search medication error records within their facility as well as from other participating facilities, using various data fields to capture specific areas of interest (e.g., category/type/location/staff). All information reported to MedMARx is anonymously submitted and the submitters identity is unknown both to the USP and to other hospitals in the system. MedMARx provides users the ability to document where in the medication use process (i.e., prescribing, transcribing, dispensing, administration, monitoring) errors occur allowing targeted assessment of specific process components. It enables users to review the causes and contributing factors (e.g., computer entry) associated with errors facility-wide, thereby identifying specific "problem-prone" systems or processes that may need changing.

Currently, there are over 500 MedMARx subscribers; approximately 40 of these are based in California. Hospitals in MedMARx have begun creating a valuable database, with over 6000 reports submitted in its first year of operation (1999) and over 40,000 more reports in its second year (2000). Now in its third year, over 175,000 reports have been submitted to the MedMARx database since its inception.

What Has Been Learned

Research by USP on both the MER and MedMARx databases has yielded valuable information that can help guide pharmacists and other healthcare practitioners in their quality assurance and performance improvement initiatives. A recently published article detailing errors identified in pediatric patients is an example of such research.[3] The study found that 31 percent of MER and 5 percent of MedMARx reports identified as involving pediatric patients were cited as harmful errors. *Improper dose/quantity* (47 percent) was the most frequently reported type of pediatric error in the MER database, while *omission* (27 percent) and *improper dose/quantity* (25 percent) were cited as the most frequent pediatric error types in MedMARx. The top products most often involved included intravenous fluids (including premixed and extemporaneously compounded preparations), acetaminophen, and gentamicin.

Other data compiled from MedMARx and publicly released last year[4] found that:

- Reported errors that cause harm are an extremely low percent of total errors—approximately 3 percent
- "Omission" (29 percent) and "failure to follow a procedure or protocol" (12 percent) were the two main *causes* of a medication error.
- Distractions and workload increases were most frequently cited as *contributing factors* related to the top two causes of error.

[i] *This definition is more inclusive than that used by the California State Board of Pharmacy.*

- Insulin, morphine, and heparin were the drugs most frequently reported as being associated with errors causing harm

The finding that most reported errors do not cause harm supports a widely held view that "near misses"– as well as errors that can cause harm–should be collected and can be extremely useful in promoting patient safety. Many hospitals currently have some type of patient safety or medication safety/error committee as part of their overall quality assurance program. MedMARx is structured to capture key details in a manner that allows for a more thorough analysis (including a root cause analysis) of the error incident. The customized reports generated through the MedMARx program are beneficial in focusing multidisciplinary attention and resources on the issue of medication errors.

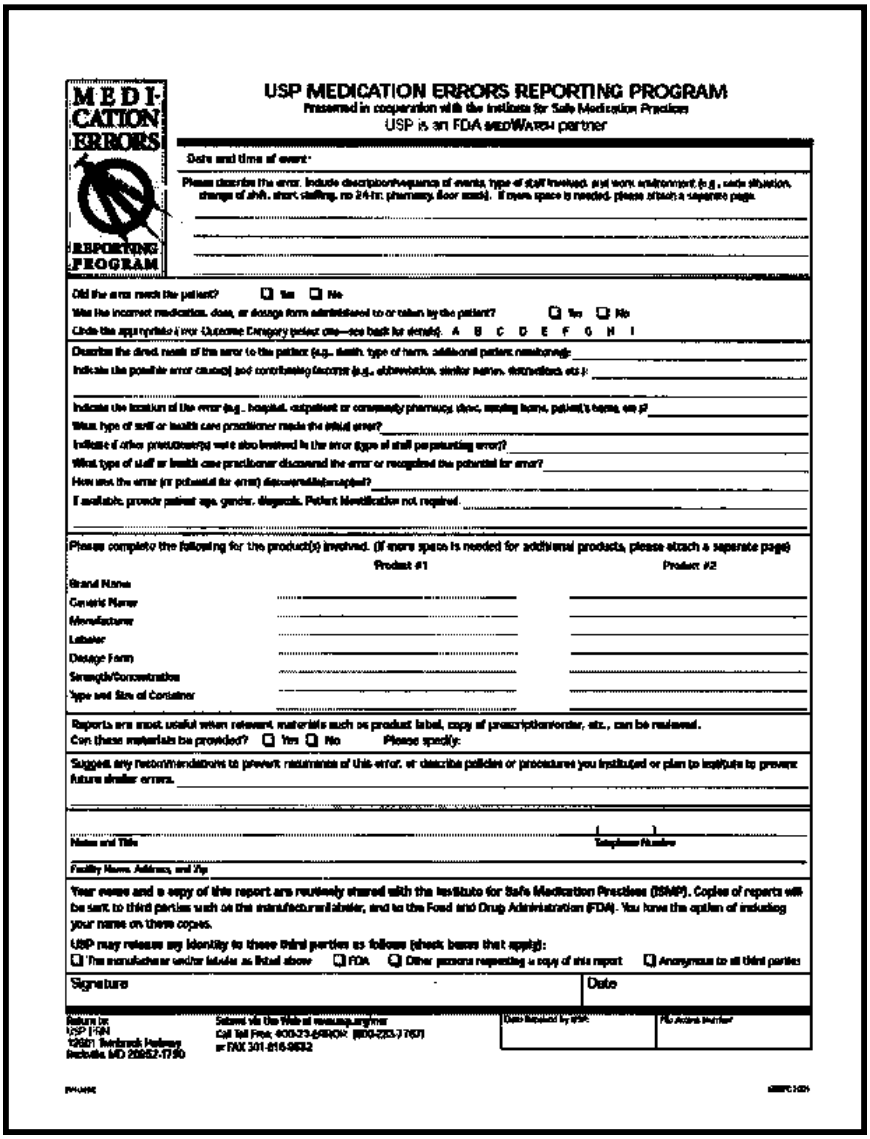
The JCAHO Safety Standard

Implementing a multidisciplinary, blame-free, proactive approach to medication errors is also part of the intent of the patient safety standards implemented in July 2001 by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO). The standard requires hospitals to establish a defined safety program – including systems for internal and external reporting of medical and health care errors. Data collected through internal and external reports are then to be used to identify risk and improve patient safety.

Although the role of the pharmacist is not identified specifically in these standards, medication use has been identified as a high-risk process.[5] However, given the complexity of the medication use system within hospitals and the frequent occurrence of adverse drug events, it is widely accepted that

Figure 1.
*The form used to submit errors to the USP Medication Error Reporting Program.**

**Source: USP Medication Errors Reporting Program, Rockville, MD. Used with permission.*



MEDICATION ERRORS REPORTING PROGRAM

USP MEDICATION ERRORS REPORTING PROGRAM

Presented in cooperation with the Institute for Safe Medication Practices

USP is an FDA MEDWatch partner

Date and time of event:

Please describe the error. Include description/sequence of events, type of staff involved, and work environment (e.g., code situation, change of shift, short staffing, no 24-hr. pharmacy, floor stock). If more space is needed, please attach a separate page.

Did the error reach the patient? ☐ Yes ☐ No

Was the incorrect medication, dose, or dosage form administered to or taken by the patient? ☐ Yes ☐ No

Circle the appropriate Error Outcome Category patient one—see back for details: A B C D E F G H I

Describe the direct result of the error to the patient (e.g., death, type of harm, additional patient monitoring):

Indicate the possible error cause(s) and contributing factor(s) (e.g., abbreviation, similar names, distractions, etc.):

Indicate the location of the error (e.g., hospital, outpatient or community pharmacy clinic, nursing home, patient's home, etc.):

What type of staff or health care practitioner made the initial error?

Indicate if other practitioner(s) were also involved in the error (type of staff participating in error):

What type of staff or health care practitioner discovered the error or recognized the potential for error?

How was the error (or potential for error) discovered/intercepted?

If available, provide patient age, gender, diagnosis. Patient identification not required.

Please complete the following for the product(s) involved. (If more space is needed for additional products, please attach a separate page)

	Product #1	Product #2
Brand Name		
Generic Name		
Manufacturer		
Labeler		
Dosage Form		
Strength/Concentration		
Type and Size of Container		

Reports are most useful when relevant materials such as product label, copy of prescription/order, etc., can be reviewed. Can these materials be provided? ☐ Yes ☐ No Please specify:

Suggest any recommendations to prevent recurrence of this error, or describe policies or procedures you instituted or plan to institute to prevent future similar errors.

Name and Title Telephone Number

Facility Name, Address, and Zip

Your name and a copy of this report are routinely shared with the Institute for Safe Medication Practices (ISMP). Copies of reports will be sent to third parties such as the manufacturer/labeler, and to the Food and Drug Administration (FDA). You have the option of including your name on these copies.

USP may release my identity to these third parties as follows (check boxes that apply):

☐ The manufacturer and/or labeler as listed above ☐ FDA ☐ Other persons requesting a copy of this report ☐ Anonymous to all third parties

Signature Date

Return to:
USP MEDMARX
12601 Twinbrook Parkway
Rockville, MD 20852-1790

Submit via the Web at www.usp.org/mer
Call Toll Free: 800-23-MEDMARX (800-233-7627)
or FAX 301-816-8532

Date Received by USP | No. Active Number

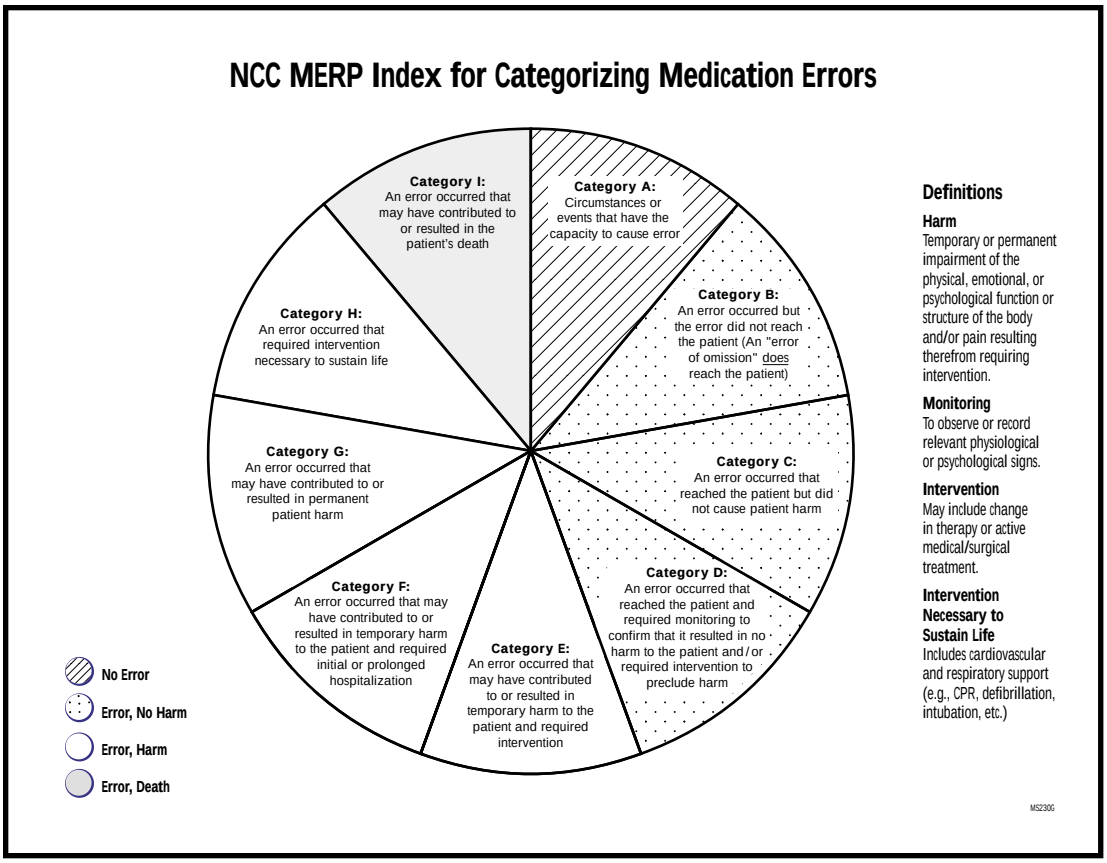


Figure 2.
2001 National Coordinating Council for Medication Error Reporting and Prevention.

the intent of the JCAHO standards supports both a focus on medication safety and the role of pharmacists in improving safety. MedMARx supports hospitals' compliance with the new JCAHO standards by prospectively identifying areas of the medication use process that are high-risk/problem-prone, facilitating both internal and external confidential reporting, facilitating root cause analysis of sentinel events, and determining opportunities for system improvements.

Conclusion

The United States and other countries around the world are focusing to an increasing degree on quality enhancement systems that improve the quality of care and promote patient safety. This focus has been heightened by reports from the Institute of Medicine and elsewhere indicating that errors in a health care system can be a significant cause of morbidity and mortality.[6] A key component of any quality enhancement system is reporting. For this reason, USP expects its MER and MedMARx programs to have a positive impact upon public health. Building a national medication-error database can contribute to the establishment of "better practices," reduce medical costs, and improve medication use systems that ultimately lead to better patient care.

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The Quest for Quality:
A Basic Review

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The ultimate goal of a pharmacy quality assurance program is to promote medication safety. Quality and patient safety terms, concepts, and principles are continually being redefined as professional and regulatory standards and expectations change. Many of these terms are used interchangeably, which can be confusing for those less familiar with their precise definitions, meanings, and nuances. For example, terms such as "quality assurance," "total quality management," and "continuous quality improvement," are frequently used interchangeably. Yet, each has a slightly different meaning and implication within the context of health care.[1-4] Nevertheless, to minimize confusion here, continuous quality improvement (CQI) will be used, as it best captures the intended meaning of the term "quality assurance" used in SB 1339. The intent of this article is to provide a brief review of CQI principles and the steps necessary to implement a successful quality improvement program to meet California's quality assurance requirement.

What is Quality?

We all have a basic understanding of the word "quality" and most of us would probably recognize it if we saw it. But, what exactly does it mean? One definition of quality, as it applies to health care, is "meeting or exceeding valid customer requirements" when providing a product or service.[1] Thus, to provide quality services, we must know who our customers are and what they need or require of us.

Quality can be transparent and therefore may not be easily recognized. This is especially true in pharmacy, where there is a lack of established quality standards or thresholds against which to measure performance. For example, what is the quality standard or safety threshold for ensuring safe medication use? Is there a safe number of prescriptions to be filled per hour? Is there an acceptable time frame for medications to reach the patient once prescribed? Is there an acceptable number of medication-related errors that can be allowed per shift, or per day?

Medication errors can occur during the medication use process for many reasons. Decisions are made under tremendous time constraints or during high levels of stress. Health care providers may be faced with information overload, limited resources, or inadequate, ambiguous, incomplete, or even erroneous information. These may all be viewed as circumstances beyond our immediate control. A quality improvement program provides a structure in which problems can be identified, documented for pattern recognition, and then analyzed for better understanding. What is learned through the process can then be shared and used to propose strategies or methods to prevent future occurrences. Ideally, this is a continuous effort, requiring commitment from all of the participants in a given process or service, such that system flaws are transformed into improvement opportunities. A CQI process allows us to reflect on what was experienced, conceptualize what happened, and put the lessons learned into practice to prevent future mishaps.

Where to Start?

Designate a process improvement team.

One of the first steps when implementing a quality improvement program is to identify those individuals who will participate. Ideally, that should include all members of the pharmacy staff – pharmacists, pharmacy interns, pharmacy technicians, and clerks. Everyone who contributes to the process of dispensing and furnishing medications to patients should be included, because quality requires a team effort. Bring everyone together regularly to discuss problems that have occurred and brainstorm solutions that are likely to be effective. Depending upon the size of the pharmacy or organization, the whole team, selected members, or administrative staff will be responsible for further analysis and implementation of process changes.

People involved in all stages of the process need to understand how important their contributions are to the whole effort. All members of the pharmacy team should understand the entire workflow process. In the community pharmacy this includes how prescriptions are taken in, how they are filled, how they are stored, and how they are dispensed. In the hospital it might include how drugs are procured, how orders are written and processed, how drugs are stored, and how medications administered. Every pharmacy will be unique in this regard, but it is imperative that all participants in dispensing or drug distribution understand the whole process.

Create a culture of safety

Blaming is not productive. Employees will feel more inclined to report errors and participate in resolving problems if the environment is non-punitive. No one makes an error on purpose, but health professionals are human beings. The rigorous education and training of licensed health care providers emphasizes error-free practice, where mistakes are unacceptable.[5] These high standards of practice result in blaming individuals when errors occur, which creates pressure to hide or cover up mistakes. An environment of trust and a willingness to learn from mistakes, either our own or those of others, is important to preventing the same types of errors from reoccurring.

Think in terms of systems and not individuals

Rarely can one individual alone cause an error. Focus on the process or system design and look for ways to improve it. Look for steps that can be eliminated or simplified and ways that procedures can be standardized. When possible, implement protocols and checklists to minimize or avoid reliance on memory. Improve access to important information and take advantage of computer forcing functions and alerts.

Recognize that there are multiple causes that contribute to any error. Systematically collect data and base decisions on that data, not on opinions. A multi-disciplinary approach to problem solving or process redesign is often necessary.

Methods and Tools

There is a whole body of literature devoted to CQI methods and tools, which is beyond the scope of this article. The reader is referred to one of the many texts in this field for further study.[1-4] Quality improvement experts generally agree the following key steps are part of any CQI initiative:

- The process is described and sources of variation from the intended outcomes are identified
- The team conducts an in-depth analysis to clarify the sources of variation and extent of problems
- The team weighs alternatives and makes decisions about how to reduce variations
- The team implements one or more of these alternatives and measures how that affects the process

Many texts in the industrial and health care literature refer to the "seven quality tools." These are flow charts, cause-and-effect diagrams, checksheets, histograms, Pareto charts, control charts, and correlation analysis. The most useful of these and some of the more common CQI method are briefly described below.

Quality improvement tools

Flow charts and diagrams help members of the team visualize all the steps in a given process. For example, when an error occurs and a meeting is convened to look at possible causes and solutions, the main steps leading up to the error can be diagrammed in the order in which they occur. These may be further subdivided, focusing on the points where decisions are made or where errors are likely to occur.

Cause-and-effect diagrams are useful when brainstorming the underlying causes of an event (see Figure 1.). They are also known as Ishikawa diagrams (after Kaoru Ishikawa who introduced a method for evaluating root causes of problems in the 1960s) or fishbone diagrams (because when completed, they resemble the skeleton of a fish). This technique begins with identifying the problem and drawing it as the end result, as if backbone of a fish. Once the main stem has been identified, contributing factors leading up to the end result can be added as branches off the main stem. For each of these, root causes can then be identified. This type of schematic is especially useful, because it enables a group to visualize multiple contributing factors and underlying root causes in one diagram.

Checksheets are another common tool and are used to record data in a way that facilitates analysis. The number or frequency of an occurrence can be tabulated, for example, by time of day or day of week, to identify peak periods when an event occurs. An example of a checksheet is the form used to document process errors, which appears as Figure 1. in the previous article, "Tools for the Reflective Practitioner: Using Self-Monitoring, Personal Feedback and Goal Setting to Reduce Error."

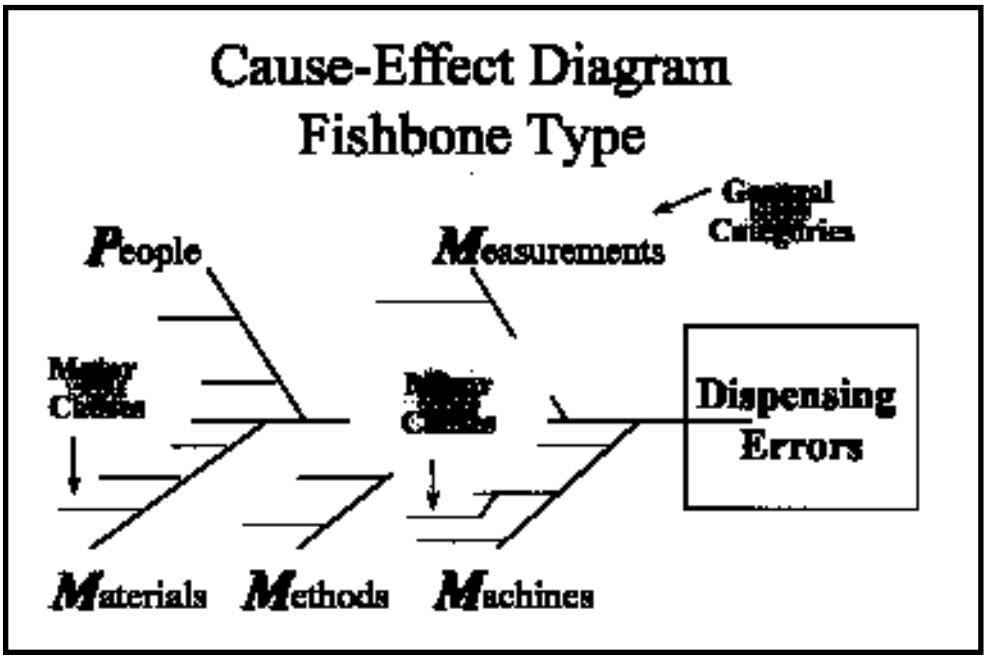

Figure 1. Cause-and-effect Diagram

Quality improvement methods

Depending upon the size and resources available to the pharmacy or pharmacy organization, the methods selected for CQI may be simple or fairly complex. It is important to focus on what is manageable for a given pharmacy to avoid getting bogged down in the process.

FOCUS-PDCA. W. Edwards Deming, one of the first American proponents of quality improvement in the business arena, popularized the "plan-do-check-act" (PDCA) cycle, which was originally published by Walter Shewhart at Bell Laboratories.[3,4] During the 1980s, the Hospital Corporation of America (HCA, now part of Columbia Health Care Corporation) incorporated Deming's concepts into its FOCUS-PDCA model, providing the healthcare industry with a common language and framework for CQI.[1,3,4] (See Figure 2.)

Find a process to improve

Organize a team that knows the process

Clarify current knowledge of the process

Uncover/understand causes of process variation

Select the process improvement

Plan the action aimed at the problem

Do perform a test or pilot study (small scale)

Check/study analyzing the impact/effect of the action

Act to fully implement and continue to improve

Figure 2. FOCUS-PDCA Model

Root Cause Analysis (RCA). This is a method for identifying the basic or causal factors that underlie variations in performance, including the occurrence or possible occurrence of a sentinel event. A root cause analysis focuses primarily on systems and processes, not individual performance. It progresses from special causes in clinical processes to common causes in organizational processes and identifies potential improvements in processes or systems that would tend to decrease the likelihood of such events in the future, or determines, after analysis, that no such improvement opportunities exist. Healthcare organizations are required by JCAHO to perform RCA's for sentinel events and reporting of these events to JCAHO is encouraged, but not required. JCAHO's RCA statistics have shown medication errors (12 percent) to be the third most commonly reported or discovered category, after suicide (17 percent) and operative or post-operative complications (12 percent). Therefore, since the initial publication of the Joint Commission's *Sentinel Event Alert* in 1998, several issues have been devoted to the topic of medication errors. These include the identification, prevention, and reporting of specific types of medication errors either reported to JCAHO as part of the sentinel event reporting system or identified by JCAHO at the time of survey.

Failure Mode and Effects Analysis (FMEA). FMEA, as described in the previous article, "Building a Safer System: Experience of Other Industries" is a proactive method to prevent errors with potential harm from reaching the patient. It is a systematic assessment of a system or process that enables one to determine the location and mechanism of potential failures. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is now requiring organizations to use proactive techniques such as this to identify potential risk points or failure modes.[5]

IMADIM. This is a method used by one academic medical center in California. It somewhat parallels the FOCUS-PDCA method and meets the intent of performance improvement. (see figure 3.)

Conclusion

There are numerous CQI tools and methodologies available that may be used or adapted for use by individual pharmacies. The goal of each is to provide a structure for identifying system problems and recognizing opportunities for improvement. The most successful of these quality improvement models move quickly from problem identification to problem resolution and prevention, without exhausting resources or team members.

IMADIM	
IDENTIFY	Identify the process for improvement • Develop your problem statement using clear, concise, and measurable terms. Identify the Team • Identify individuals involved in the project.
MEASURE	Measure current performance Identify data sources for measurement of the problem Benchmark • Use comparative data when possible
ANALYZE	Analyze current processes • Look at all steps in the process • Include input from a cross section of project members • Analyze the data using CQI tools
DESIGN	Design the improvement • Using your data, analyze and design a specific course of action
IMPLEMENT	Implement Process Improvement • What are the implementation steps? • Who will be involved? • What are the milestones?
MEASURE	Measure Performance • What will be the methods for monitoring progress? • How will you make conclusions as to whether the implementation actions were effective?

Figure 3. The IMADIM Method

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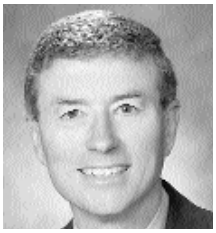
Continuous Quality Improvement Programs: **Experiences In Different Pharmacy Settings**



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Continuous quality improvement (CQI) programs exhibit commonalties across various business settings. All CQI programs, independent of methodology, involve the identification of a problem, analysis of the problem, implementation of a process to minimize the problem, and then testing the outcomes of implemented processes. CQI programs that have been established by others may be reviewed and possibly modified for use in our individual practice settings. Distribution and dispensing of medications share common processes, regardless of practice settings, and review of CQI programs from hospitals, chain drug stores, independent community pharmacies, and long-term care facilities can provide useful roadmaps. This article is intended to share experiences that pharmacies in different settings have had with their CQI programs.

Experiences of A Chain Store Pharmacy.

Background

Organizations commonly utilize policy and procedure documents to record the rules and regulations governing the operations of their enterprise. Policies are general statements of an organization's philosophy on specific operational issues and procedures define a step-by-step process for the implementation of those policies. Policies and procedures are often identified by a title, a particular coding system, date of implementation, date of revision, and some indication that the particular policy and procedure of a unit meets the approval of the organization.

One chain store pharmacy began its quality assurance (QA) program by assembling individuals to develop a plan and then wrote policies and procedures to support that plan. After review and feedback from various individuals, this chain pharmacy developed an instructional video to describe the company's new QA program. It focused on the management and prevention of pharmacy errors related to the dispensing of medications. Although preparation of a videotape is not necessary for the dissemination of a QA program, this approach was selected because of a need to facilitate communication of information to a large number of employees. The videotape also facilitated standardization of the presentation. Employees were subsequently instructed to read the relevant policies and procedures and to acknowledge formally, by means of their signatures, that these were read and understood. These procedures also described a process for educating future new employees on this QA program.

Specifics

In this QA program, pharmacy incidents or errors were defined. Demographic data (e.g., patient information, nature of incident, personnel involved, date and time of incident, outcomes) is also collected, not for the purposes of affixing blame, but to assist in analyses to identify contributing factors. After appropriate study of the probable cause(s) of the incident and action(s) undertaken, the specific pharmacy error is reviewed with the individuals who were involved. Subsequently, this information is shared with other staff members to reinforce the utilization or improvement of proper procedures.

An investigative form was developed for the collection of pertinent information related to a pharmacy error. The pharmacist who is notified of the incident is responsible for completing the form and submitting it to a central location. Instructions for these steps are provided in the videotape and in the written policies and procedures. This pharmacist also is responsible for notifying other managers (e.g., the district pharmacy manager, store manager, and the pharmacist in charge) that the investigative form had been completed. An electronic summary of the report is available to the pharmacist at the store level and is password protected.

The procedures for this QA program provide guidance for sharing information related to a specific pharmacy error with the California State Board of Pharmacy. They also provide reassurance that the Board of Pharmacy's review of the error is to assure the safe distribution of prescription medications by adherence to established procedures. The QA program establishes a process for management oversight to identify trends in prescription incidents to assist in the development of both new procedures and better systematic processes. In addition, a process for communication of these findings to affected units in the organization was established.

Best Practices used by this Pharmacy

This chain pharmacy's QA program emphasizes the prevention of prescription errors through several checks and balances:

1. Standardized procedures during the dispensing process

- Verify all telephoned prescriptions by verbally confirming the patient's name, medication name, quantity to be dispensed, directions for use, and the name of the authorized prescriber.
- Fill the prescription from the hard copy of the prescription rather than from the generated label accompanying the prescription.
- Verify that each filled prescription involved a process for comparing the NDC number on the filled prescription label against the stock container.
- Develop a bar code scanning process that tracks and verifies that "systematic" checks are in place throughout the dispensing process.

2. Standardized procedures at the time the medication is presented to the patient

- At the time of the patient consultation, ask the patient for his or her full name and the name of his or her authorized prescriber (e.g., physician) for comparisons against the label affixed to the medication container.
- Visually inspect the medication against the hard copy of the prescription before giving the patient the medication for all new prescriptions.

Experiences of An Independent Community Pharmacy.

Background

The policies and procedures for an independent community pharmacy should be similar to that described above for a chain store pharmacy. In essence, policies and procedures are written after front-line personnel have developed a plan. The plan must then be communicated appropriately to all affected personnel, who should acknowledge their understanding of it. Procedures for data collection and for analyses of the processes surrounding a medication error also need to be clearly understood. Again, the issues of problem identification, analyses, implementation, monitoring outcomes, and subsequent reevaluation of the procedures to further improve the program are similar to those for all QA programs.

Best Practices used by this pharmacy

In the independent community pharmacy, the following practices demonstrate that procedures for minimizing medication errors can be standardized.

1. Generation of prescription order.

- Use facsimile (fax) machines to minimize errors from verbal telephoned orders.
- Use fax servers that utilize computer-generated transmission of prescription orders to alleviate the problems associated with illegible handwriting.
- Be careful with computerized physician order entries (CPOE). While they alleviate problems with illegible handwriting, they are still susceptible to errors (e.g., incorrect selection from menu-driven screens of drug, dosage forms, doses, or directions for use). CPOE can also create errors because of incompatibilities at the interface between the hardware and software of the physicians' office systems and the pharmacy system.

2. Interpretation of prescriptions.

- Obtain clarifications whenever the prescription order is unclear and requires an interpretation (e.g., "look-alikes" and "sound-alikes").
- Enter the diagnosis on the prescription label (e.g., one tablet daily for hypertension) to lessen the potential for error.

3. Obtain pertinent patient data

- Obtain allergy histories while gathering insurance and other demographic data.
- Obtain information on concurrent disease states to facilitate collaborative drug therapy management and prevent potential adverse effects (e.g., ulcerogenic medications in a patient with an active peptic ulcer).

4. Computer data input

- Use the NDC (National Drug Code) from the medication stock bottle wherever possible to assist in the identification of the correct medication. The effort to input the NDC of a drug into the data entry process necessitates review of the medication prior to computer entry. In addition, write the NDC from the medication bottle on the prescription order for each new and refill prescription, especially if the NDC can be printed on the computer-generated label that is to be affixed to the medication container.
- Be careful when using menu-driven screens to select drugs, doses, and dosing instructions and initiate a process for a double check whenever possible.

5. Medication packaging

- Fill one prescription at a time, especially when medication orders are grouped together on one prescription blank and accompanied by multiple labels.
- Read the written prescription before reading the computer-generated label, and then check the label for accuracy.
- Do not leave a medication container unlabeled (i.e., complete the labeling task before responding to interruptions).
- Place completed multiple prescriptions for a patient banded or packaged together in an uncluttered storage area to minimize the delivery of a medication vial to the wrong patient.

6. Delivery of medication to the patient.

- When consulting with the patient, ask the patient for his or her first and last names and the name of the physician, and compare this information to the information on the label that is affixed to the medication container.
- Open the container and place several tablets or capsules onto the cap of the medication vial to show the patient and visually ascertain that the identity of the medication is consistent with the labeled contents of the medication vial.
- If your pharmacy system has bar code scanning capabilities, utilize this technology to confirm that the right patient is about to receive the right drug.

Many of the above best practices can be rewritten as procedures in support of a pharmacy's quality assurance policy. Adherence to written procedures is intended to standardize a process (e.g., dispensing drugs) and to maximize the outcomes

from that process (e.g., decreasing the probability of a medication error). Although deviations from standardized procedures may be associated with ethical, professional, and legal implications, a standardized approach can decrease liability by decreasing the potential for adverse outcomes. Standardized procedures that are analyzed and updated periodically can improve the quality of pharmaceutical care to patients, decrease errors, decrease costs, and increase profitability.

Experiences of a Community Pharmacy's QA Implementation

The following describes a community pharmacy's implementation of a quality improvement program that addressed dispensing accuracy and medication errors. The pharmacy was notified by its customers of several medication dispensing errors, which occurred over a two-month period. As a result, pharmacy management instituted quality improvement principles to implement a system of improved internal surveillance of dispensing practices and process analysis of dispensing data.

A well-designed quality improvement program must be based on high standards and grounded in established standardized procedures. In this case, there were no clear standardized procedures for checking the accuracy of dispensed prescriptions and no consistency in how the small staff of pharmacists and technicians documented that the prescription was filled with the correct medication. These pharmacists developed with the staff procedures that not only achieved the purpose of content verification, but that were also acceptable to each staff member. In this case, a procedure utilizing NDCs was added to the prescription filling process. The NDC for a drug was to be placed on the label of the medication vial and compared against the NDC on the manufacturer's stock container that was used to fill the prescription. The pharmacist's initials on the hard copy of the prescription signified that this step occurred.

Analysis of the medication dispensing errors that had occurred revealed that sound-alike drugs were inaccurately dispensed in two cases and fast-moving drugs confused in two others. The pharmacy's dispensing process allowed for accumulation of manufacturers' containers of fast-moving drugs on the dispensing counter. On a busy day, this could clutter the dispensing area and lead to inaccurate product selection. A new practice of re-shelving items at least every 15 minutes was instituted. A reference listing of common sound-alike drugs was also shared with staff and posted. Additionally, selected items were assigned new locations on the shelves to prevent two sound-alike drugs from being shelved in close proximity to one another.

Most importantly, two forms were developed and implemented. A form for errors that are identified *after* prescriptions are dispensed captures detailed information about the medication error and patient sequelae. These infrequent occurrences can now be tracked and analyzed for common causes and possible solutions. When a dispensing error is reported, the results of the pharmacy's investigation and resultant process changes are shared with the "customer" reporting the error, whether a patient, nurse, or physician. Although resistant at first, the staff later agreed that sharing this information would be helpful in re-establishing credibility with their customer(s).

The second form, named a discrepancy diary, captures errors that occur and are corrected *during* the dispensing process. Occurring more frequently than actual dispensing errors, compiling this data can result in a relatively quick identification of dispensing processes that are vulnerable to the introduction of errors and opportunities for improvement. This not only prevents future errors, but can increase efficiency by eliminating the workload associated with correcting them.

Discrepancies logged in the diary over a two-week period revealed that labels for topical medications prescribed by a dermatology practice were frequently re-generated when one specific technician was at the computer. The pharmacists met with this technician and together they developed a process to better meet the expectations for labeling these medications. Further review of the diary also noted that pharmacists frequently rejected prescription labels for liquid medications. Again, the pharmacists met with the pharmacy technicians and developed a new standardized labeling format.

The pharmacy staff now meets regularly as the Quality Improvement Team to review both the prevented errors in the discrepancy diary and the medication-dispensing errors. These meetings have resulted in the implementation of new procedures to improve services, beyond the medication error program. The dispensing staff has coalesced and now considers itself more of a team. This positive attitude and management's perspective that errors and discrepancies should be embraced as opportunities for analysis and improvement, have led to a decrease in discrepancies and medication errors as well.

Experiences of A Long-Term Care Pharmacy

Skilled nursing facilities, assisted-living communities, and residential-board and care homes commonly contract with one pharmacy to provide pharmaceutical services and prescription medications for the majority of their residents. These extended care facilities and their professional staff members are, therefore, important customers of the pharmacy in addition to its more obvious customers (i.e., patients, authorized prescribers).

Nursing facility operations are highly regulated by both federal and state agencies. One California requirement calls for timely administration of certain medications such as anti-infective agents and drugs that are critical to symptomatic relief (e.g., analgesics, anti-emetics, anti-diarrheal agents). Unless ordered "stat," these agents should be administered within four hours of being ordered. Medications NOT administered within four hours can be deemed medication errors by state health licensing surveyors during annual inspections or whenever a complaint is investigated. Although not strictly within the purview of the pharmacy and despite timely dispensing by the pharmacy, late administration of the medication can lead to a medication error for the pharmacy's customers, the facility and its patients.

Pharmacies within long-term care facilities are uncommon. Although emergency supplies of medications are allowed, the content and quantities are tightly controlled. Pharmacies design their emergency supplies to best serve the needs of their customers and a timely delivery process is critical to their success. Distance and traffic can be significant challenges to optimal outcomes. Without clear standards, procedures, and on-going monitoring of timeliness, a pharmacy can jeopardize its patients and the facilities it serves.

A Southern California institutional pharmacy exclusively serving long-term care facilities conducted a customer satisfaction survey to assess the level of satisfaction with their services and to determine which services were most important to their customers. Results clearly indicated that in addition to medication dispensing, timeliness of delivery was of prime importance. Several facilities indicated that they had received state deficiencies for medication errors resulting from medications not being available on time. The findings of the pharmacy's own consultant pharmacist the previous quarter reinforced the problem of timely delivery and administration of medications.

This pharmacy is located in a large metropolitan area with access to freeways that are becoming increasingly congested. With business growing at farther distances from the pharmacy, delivery became an issue. The pharmacy staff understood the importance of the four-hour requirement, but until the customer satisfaction results identified this as an issue, the pharmacy had not developed an ongoing system to measure performance. They now knew they had a problem, but did not know how serious it was or what might be the underlying cause(s).

Multiple steps in the medication use process must be completed in a timely and coordinated manner to achieve the desired outcome of timely administration. These steps involve many different individuals and include timely noting of the order by the facility nursing staff, properly notifying the pharmacy (i.e., fax, phone) of a time-sensitive order, consistent pharmacy intake and dispensing procedures that properly differentiate a time-sensitive order from routine and refill orders, and staging of deliveries. The latter involves taking medication administration times at the facility and traffic into consideration when determining facility delivery order within a certain delivery run. Additionally, at the facility level, staff must recognize when there is a time-sensitive order included in a delivery and must administer the medication in a timely manner. Although the last two steps are not technically within the pharmacy's control, they are important to achieving optimal outcomes when assessing performance. The complexity of the process illustrates several areas of vulnerability that might contribute to overall success.

To address this problem, pharmacy management first established an indicator of timely processing of time-sensitive orders and a system to monitor performance. The goal was to deliver 100 percent of time-sensitive orders well within the four-hour window. The pharmacy first designed a method for identifying and tracking of these orders as they progressed through the dispensing process. The time orders were received by phone or fax was already being documented for every order, but time-sensitive orders were not differentiated in any way. Pharmacy staff responsible for data input were then instructed to highlight time-sensitive orders. On a daily basis, dispensing times were calculated for time-sensitive orders delivered the previous day. This was done by noting the time an order was received by the pharmacy and the time the staff at the facility signed for the delivery. Orders outside of the four-hour window were noted. The consultant pharmacists were given a list of these so they could follow-up on the actual administration of medications, on a random basis, when they were in the facilities.

TALKING TO PATIENTS FOLLOWING A PRESCRIPTION ERROR

Do

1. Involve the pharmacist immediately.
2. Apologize – speak to the patient directly.
3. Ask if any of the incorrect medication was taken. If so, find out how much the patient took and for how long.
4. Ask how the patient is feeling – Show your concern with you tone of voice and body language.
5. Communicate to the patient that he/she received incorrect medication or the wrong strength of medication.
6. Ask the patient to return the incorrect medication.
7. Take immediate action to provide correct medication to the patient.
8. Counsel the patient.
9. Notify the prescriber with the details of the error and what the pharmacist has done to correct the error.
10. Follow up with the patient the next day.
11. Explain that the pharmacy is investigating how this happened so that it will not happen again.

Don't

1. Make excuses.
2. Use a defensive tone of voice.
3. Take any error or potential error lightly.
4. Delegate the responsibility to handle the error to a non-pharmacist.
5. Require the patient to make the effort to obtain the correct medication.
6. Violate patient confidentiality.
7. Apologize via a voice mail or answering machine.
8. Underestimate the concern of the patient.
9. Assume the patient is okay.
10. Make the patient wait.

After identifying that a prescription error has occured, some pharmacies deliver the appropriate medication to the patient, pick up the inappropriate medication, refund the original prescription copay or price, and provide the correct medication without charge.

The data were surprising. Timely delivery was a larger problem than previously realized. The indicators of timely delivery ranged from 70 to 100 percent, with the former being more common than the latter. The prevalence of time-sensitive orders was much higher than the staff realized and several specific antibiotics that were not currently in the emergency supply were more commonly dispensed than previously thought. Certain delivery times and days of the week were more problematic. When delivery personnel were matched with the indicator data, it appeared that certain staff seemed to perform much better than others.

In order to identify root causes and solutions, the management shared the results with all staff involved in the various steps necessary for timely delivery. The consultant pharmacist shared the results of the quality improvement study. The pharmacy staff was amazed at the complexity of the overall task and how many individuals were involved. The consultant data revealed that a number of facilities had higher prevalence of orders outside the four-hour window than others, despite timely pharmacy delivery. A further investigation determined that in many of these cases, especially later in the day, the delivery containing the time-sensitive orders was not checked in by facility staff until after the four-hour window. Delivery staff with excellent indicator data shared their procedures for determining order of delivery. It became apparent that the pharmacy did not have a procedure for notifying delivery personnel that timed orders were within their delivery. Some already took this into account as part of their routine, but it was not standardized. Since the pharmacy business and traffic had grown, this inconsistency was leading to inconsistent outcomes.

Discussion by this "team" of involved pharmacy staff recommended several possible solutions, which were implemented sequentially while continuing to monitor performance. Procedures were added to better mark time-sensitive orders as they progressed through the dispensing process, to mark delivery bags containing time-sensitive orders with brightly colored stickers, to design delivery runs around these orders, and to notify nursing staff at the facility when a delivery contained time-sensitive medications. In addition, the emergency supplies of oral medications at the facilities were revised to better meet the facilities needs.

The pharmacy continues to measure this quality indicator, although now on a more random and periodic basis. What was initially identified as a problem through a customer satisfaction survey resulted in changes in process for both the

pharmacy and the facility, yielding higher quality of care for the ultimate customer, the patient.

Experiences of a Hospital Pharmacy

Background

One of the first steps of a quality assurance plan involving documentation/assessment of medication errors is an effective reporting mechanism. In 1999, a hospital pharmacy implemented an on-line incident reporting system, which significantly improved the management of medication errors. Timely reporting of medication errors is essential for accurate data gathering while memories are still fresh and documents such as medication orders or faxes are still easily retrievable. Once a staff member submits a medication-related incident report, an e-mail notice with a link to the incident is immediately sent to the manager of the person who reported the medication error and to the Medication Safety Pharmacist. The Department of Risk Management also has access to all incident reports. These steps help to ensure that a medication-related incident will be reviewed within 48-72 hours. If another manager needs to see a copy of the report, the e-mail link can be forwarded. All who review the incident report have an opportunity to add comments pertaining to follow up actions or additional investigation. The system also documents those who review the incident report, but make no comments.

Gathering all the information needed to assess the cause and severity of an incident is an important aspect of the reporting process. Asking specific questions instead of relying on a written account of the incident is a good way to capture essential information. For medication errors or delays in medication administration, information is requested on date, time, location, as well as the name, age, and gender of the patient. Further information is requested of the individual who reports the medication error as shown below.

1) Name of the medication
2) Where in the medication process the initial error occurred. One of the following choices is selected from a drop down menu: prescribing, documenting, dispensing, administering, or monitoring.
3) Type of Error. One of the following choices is selected from a drop down menu: extra dose, improper dose/quantity, omission, wrong administration technique, wrong dosage form, wrong drug, wrong drug preparation, wrong patient, wrong route, wrong time, or other.
4) Possible Causes of Error. One of the following choices is selected from a drop down menu: calculation error, contraindicated or allergy, decimal point, illegible handwriting, look alike or sound alike products or product name, pump improper use, transcription, or other.
5) Whether the error reached the patient.
6) The result of the error on the level of care e.g., antidote administered, code blue, death, drug therapy-initiated or changed, hospitalization-initial, hospitalization-prolonged, lab tests performed or increased, oxygen administered, reversal agent administered, surgery performed, transferred to a higher level of care, or vital signs monitoring initiated/increased.
7) Results of any tests/lab data if relevant to the outcome of the error.

This hospital chose to focus on some of the more common causes of an error and provided an "other" option to capture the less frequent types of errors. To encourage voluntary reporting, a blame free environment is promoted by establishing hospital policies that prevent incident reports from being used as part of performance evaluations. "Performance deficit" as a cause of error was intentionally omitted in order to reinforce the non-punitive, systems approach to error reduction.

The on-line system has undergone multiple changes since its first implementation at this hospital pharmacy. Some manual transfer of the data must still occur in order to generate quarterly and annual reports. Plans to expand the report-generating potential of this system are under development.

The Medication-Related Events Management Program

When this hospital had the reporting mechanism in place, the next questions were, "Who should take responsibility for reviewing the errors?" "What do we do with the incident reports?" "How do we improve care?" The answer was to implement a Medication Related Events Management Program to reduce medical errors attributed to the medication use process. Two important committees were appointed, the Medication Safety Steering Committee and the Medication Process Improvement Committee. The first, a multidisciplinary subcommittee of the Pharmacy and Therapeutics Committee, has oversight responsibility for medication safety. The latter is a pharmacy-nursing committee that deals with specific issues related to these two departments.

The first phase of the plan was to develop a definition of an error, recognizing that there is value in looking at both the

HOW NOT TO HANDLE AN ERROR SITUATION:

Mrs. Jones walks up to the pharmacy counter on a Tuesday morning to question why the refill she picked up the night before was a light blue tablet instead of a white tablet. The pharmacy clerk looks inside the bottle and agrees that the tablets are blue and suggests that it is probably a different generic manufacturer.

Mrs. Jones explains that the medication is for her diabetes and that she took one of the tablets last night at bedtime and is feeling ill this morning. She wasn't paying attention to the color of the tablet when she took the drug last night. The clerk mentions that they were very busy yesterday and then calls the pharmacist to the counter.

The pharmacist talks to Mrs. Jones who again explains her concerns and is visibly upset. Meanwhile, several people have gathered around the cash register area waiting to be helped. The pharmacist says that they had a new technician working yesterday and then excuses himself while he goes to retrieve the prescription from the files for review.

Upon looking at the Rx hard copy, he sees that Rx called for Glipizide,® which is what is on the Rx label. However, he recognizes the light blue tablet to be Glyburide,® and fully understands that a prescription error has occurred.

The pharmacist tells the patient that a mistake has occurred and that he will fix the problem and dispense the correct drug right away. Before Mrs. Jones can say anything, he prepares the correct medication in a hurried fashion and hopes that no one else will notice that the pharmacy made an error.

Mrs. Jones tells the young pharmacy clerk that she is very upset about this situation and that she is not feeling well.

The pharmacist comes back to the counter with the correct medication, thanks the customer for bringing the error to their attention, and assures the patient that this error will never happen again.

Mrs. Jones says that she no longer trusts the pharmacy and will never be coming back there again.

errors that reach the patient and those that do not. In this hospital, *potential* errors are defined as mistakes that are corrected through intervention by the health care professional or the patient. *Actual* errors are errors that result in administration of a drug that deviates from the order or is given due to a prescribing error. Omission errors are considered exceptions to this definition and are considered actual errors.

Both types of errors are useful and indicate a point of vulnerability in the system. Consider the warfarin prescription that is filled with 10 mg tablets when 1 mg tablets were ordered. The patient notices the pills are a different color than usual and questions the pharmacist prior to leaving the pharmacy, thus an error is avoided. Even though the error did not leave the pharmacy, multiple system problems may be identified that caused this error (e.g., use of trailing 0, transcribed incorrectly, storage of the 1 mg and 10 mg next to each other on the shelf).

The Medication Related Events Program document includes an outline of the medication reporting process and incorporates other medication related policies (i.e., Sentinel Event Policy and the Incident Report Policy). Most pharmacy system improvements are the result of staff and management "brainstorming" sessions. Due to the complexity of the medication use system, many of the pharmacy system improvements are discussed by the Medication Process Improvement Committee to insure that changes in pharmacy procedures will have little or no negative effect on nursing processes.

Conclusion

As noted above, quality assurance programs in various practice settings have commonalties. While there may be different processes used, the steps involved when developing a quality assurance program are similar. These include:

- Developing policies and procedures – Map out your current medication use process, critically analyze it, and incorporate safety practices that are readily available in the medication safety literature.
- Developing a reporting mechanism. There is no need to re-invent the wheel. Network with other pharmacists and use the tools that are currently available, editing these to fit your practice site.
- Educating the employees who will be participating in the system.
- Fostering a blame-free environment. Use the information from errors to identify system issues or education/training issues.
- Tracking the near misses – They provide valuable information.
- Utilizing technology to minimize errors.

Fostering open, honest communication about errors. Ensure that staff all understand the results of error reporting and are involved in developing solutions.

HOW TO BETTER HANDLE THE SAME SITUATION.

Mrs. Jones walks into the pharmacy on a Tuesday morning complaining to the young pharmacy clerk that her refill for her diabetic medication that she picked up last night appears to be the wrong drug, because it is a light blue tablet instead of a white tablet.

The pharmacy clerk immediately calls the pharmacist to the counter. The pharmacist walks over and introduces himself and asks her to tell him about the problem.

Mrs. Jones tells the pharmacist that she took one of the tablets last night, not realizing it was light blue, and is now not feeling well. The pharmacist apologizes for her not feeling well and tells her that he is going to look at the prescription again to determine what the doctor ordered and what is in the bottle. He escorts her to the waiting area and suggests that she sit down while he immediately follows-up on the situation.

The pharmacist reviews the patient profile and determines that the patient has been maintained on Glipizide® for almost a year. The bottle is labeled correctly, however he looks at the light blue tablets and determines the drug is Glyburide®. The pharmacist calls Dr. Smith, Mrs. Jones' endocrinologist, and explains what happened. Dr. Smith tells the pharmacist he will note it in her chart. He confirms with the pharmacist that the correct medication will be dispensed, but that no patient harm should be caused by this error.

The pharmacist corrects the mistake and takes it over to Mrs. Jones. He explains what happened. He also tells her that while the incorrect drug is also used to treat diabetes, it was an incorrect drug for her and apologizes for the error. He assures Mrs. Jones that the pharmacy takes several precautionary steps while filling every prescription in their pharmacy.

He mentions that he has spoken to her doctor about the error and that there shouldn't be any harm from taking the one tablet. The pharmacist refunds the $25 copay that Mrs. Jones paid for the refill the night before, retrieves the incorrect medication from Mrs. Jones, and asks her if there is anything else that he could do for her now. She says "no" and thanks him for his help, but suggests they be more careful when filling prescriptions in the future.

The next day the pharmacist calls Mrs. Jones to see how she is feeling. She reports to him that she is feeling much better and is glad that nothing more serious happened due to the mistake.

A month later Mrs. Jones calls the pharmacy for a refill on her Glipizide.® She continues to be a patient of the pharmacy.

What Can Consumers Do To Protect Themselves From Medication Errors?

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Teaching consumers to be more knowledgeable about their medications is one way to protect them from medication errors. Consumers can be taught to play a greater role in their health care by encouraging them to speak up and routinely question their physicians and pharmacists about all their prescription medications, over-the-counter medications, herbals, and vitamins. As time with providers grows shorter, consumers must be advocates for their own care. They can do so if they have the tools and take responsibility for getting the proper questions answered about their medications.

Unfortunately, 96 percent of patients never ask any questions about their medications.[1] They assume that everything their doctor prescribes is correct and they believe their pharmacists will always dispense the right medicines. But this may not be the case, because physicians have less time to do their jobs and pharmacists are often overwhelmed with hundreds of prescriptions to fill. Thus, consumers must be educated to ask questions of both their doctors and pharmacists to better assure that they get the right medication and to know how to take it properly.

What questions should consumers ask?

A number of health care and consumer organizations have developed lists of the basic questions that consumers should ask when given a new prescription.[1-6] The California State Board of Pharmacy recommends:[1]

Before taking any prescription medication, talk to your pharmacist; be sure you know:

- What is the name of the medication and what does it do?
- How and when do I take it and for how long? What if I miss a dose?
- What are the possible side effects and what should I do if they occur?
- Will this new prescription work safely with the other medicines and herbal supplements I am taking?

[i] *www.smartcoalition.org*

- What food, drinks or activities should I avoid while taking this medicine?

In addition, the Board recommends that consumers be instructed to also tell their health care professionals:

- The names of all prescription and non-prescription medicines they are taking and for what conditions they take them;
- If they are allergic to any medicines;
- If they have any problems with any medicines;
- If they are or could be pregnant.

Taking Responsibility

In addition to educating consumers to ask the right questions, pharmacists should also emphasize the other things that patients can do to play a greater role in their health care. Pharmacists should encourage patients to:

- Maintain a list of all of their prescription and over-the-counter medications, as well as any vitamins, herbal products, nutritional supplements, or home remedies they take. This list should be kept up to date and carried with them at all times.
- Insist on being counseled about any new medication. It is state law for the pharmacist to provide consultation in such cases.
- Ask the pharmacist to "show and tell" every time patients receive a new or refilled medication. Have the pharmacist open the bottle and show the medication inside. Customers should question anything that looks different – a different color, shape, name, or strength of their medicine.
- Tell their doctor and pharmacist about everything they take, including herbs, nutritional supplements, and vitamins.
- Read the information that is provided with their medication and ask the pharmacist to explain anything that they don't understand.
- Follow the directions for use on the prescription label or on the bottle or container. They should not take more or less than instructed and should continue to take the medication as long as it is indicated.
- Write down any suspected problems that occur when taking any medication and report these to their doctor or pharmacist.
- Keep a list of medications that have caused problems or allergic reactions in the past and make sure their doctor and pharmacist includes this information in their medical record and patient profile.

Helping Seniors Take Control

Seniors are particularly vulnerable to adverse effects associated with medications. On average, they consume more medications than younger individuals and suffer a disproportionately higher percentage of adverse effects. One program that is available to help seniors learn to take responsibility for their medications is the Senior Medication Awareness & Training Program, SMARxT. (For more information see www.smartcoalition.org.) The SMARxT Coalition of California is a consortium of statewide grassroots organizations. In the SMARxT workshops seniors are taught the basic questions to ask of their pharmacists and physicians. They are also instructed to never make decisions about their medications, over-the-counter meds, herbals, and vitamins without first asking questions of their health professionals. A handy SMARxT wallet card is given to participants for easy reference to these questions and the seniors are taught to show this card listing all their medications, herbals, over-the-counter drugs, and vitamins to their physician every time they visit the doctor or get a new prescription. The SMARxT workshop teaches them that even if they are taking only one prescription drug, they should never buy anything else over-the-counter without first asking the pharmacist if it is safe to take along with the list of medications listed on their SMARxT card.

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4. www.safemedication.com. Website for the American Society of Health-System Pharmacists (ASHP) consumer information. "Medications and You: Preventing Medication Errors." Accessed 1/30/02
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6. www.smartcoalition.org. Website for Senior Medication Awareness & Training Program (SMARxT). "Questions You Should Ask Your Doctor and Pharmacist." Accessed 1/30/02

Resources for Additional Information

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Bibliography

To Err is Human: Building a Safer Health System
LT Kohn, JM Corrigan, and MS Donaldson (Eds.), Institute of Medicine. Washington D.C.: National Academy Press (2000)

The Institute of Medicine has drawn national attention to medical errors.
This book truly was the catalyst for bringing attention to medication safety issues.

Comments: This book provides a great overview of the medication error problem. Pertinent topics covered include reporting systems, protecting voluntary reporting systems from legal discovery, and creating safety systems in health care organizations.

Advantages: Great summary of medication error reduction strategies, including recommendations from multiple organizations. Includes summaries of medication-related studies, including descriptions of samples, data sources, results, definitions and causes/types of errors.

Disadvantages: Many of the medication error reduction strategies are pertinent for health care organizations and/or hospitals. Limited reduction strategies for independent community pharmacies.

First Do No Harm: A Practical Guide to Medication Safety and JCAHO Compliance.
Marblehead, MA: Opus Communications (1999)

As the title indicates, this book is a helpful reference for hospitals
in developing a medication safety program to meet Joint Commission standards.

Comments: Useful for the hospital pharmacists. Topics include applying systems approaches to error prevention, performing root cause analysis, designing and implementing improvement proposals and complying with JCAHO standards.

Advantages: Explains tools necessary for any quality improvement program. Includes a suggested reading list at the end of each chapter.

Disadvantage: Independent/community pharmacists may find little value in the chapters that cover JCAHO standards. However, the pharmacist-in-charge may review these chapters as many of the practice guidelines could be adapted to an out-patient pharmacy.

Medication Errors: Causes, Prevention and Risk Management

MR Cohen (Ed.) Sudbury, MA: Jones and Bartlett Publishers (2000)

Provides practical examples of risk assessment and process improvements. Identifies those medication adverse events that have resulted in patient deaths as well as specific weaknesses in the medication use processes and suggests system changes to prevent these.

Comments: Topics include identifying poor distribution practices, dosing miscalculations, packaging problems, incorrect drug administration, and patient education issues.

Advantages: This book has something for everyone. Of particular interest to all pharmacists is Chapter 9: "Preventing Dispensing Errors." This chapter does an excellent job of covering both the common causes of dispensing errors and their solutions. There is also a chapter that discusses effective use of dispensing automation that will be useful to outpatient and inpatient pharmacists alike.

Disadvantages: There are none! Great reference…it's a must have.

Medication Use: A Systems Approach to Reducing Errors.

DD Cousins (Ed.) Oakbrook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations (1998)

Provides a good overview of using the "systems approach."

Comments: Chapter 6, "Case Study on Measuring and Improving the Medication Use System," is a good reference for those attempting to outline their own reporting system.

Advantages: Explains many of the tools utilized in examining processes and identifying opportunities for improvement. Describes the process and provides a case study as an example.

Disadvantages: Primarily geared to the hospital pharmacy; however, some portions could easily be adapted to outpatient pharmacy areas.

Preventing Medication Errors: Strategies for Pharmacists

Oakbrook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations (2001)

Defines the pharmacist's role in preventing medication errors in all aspects of the medication use process (prescribing, dispensing, administering, and monitoring drugs).

Comments: The tendency to compartmentalize the medication use system is sometimes difficult to overcome. Pharmacists will sometimes focus on their piece of the medication use pie, which is dispensing errors. This book does an excellent job of encouraging the pharmacist to look at all stages of the process to improve medication use.

Advantages: Illustrates the pharmacists' ability to impact medication use at all levels.

Disadvantages: Focused primarily on hospital practice.

Web Sites

American Pharmaceutical Association www.aphanet.org
Comments: *Offers a variety of books and products and has useful links to other pertinent sites.*

American Society of Health-System Pharmacists www.ashp.org
Comments: *Offers products and services. The Practice Resource Section includes a new Patient Safety site. This site includes an extensive bibliography as well as a newly developed "Medication Use System Safety Strategy (MS3): Phase I of the ASHP Medication Safety Officer Project." The document provides a systematic approach for healthcare organizations wishing to design, implement, and maintain safe medication use systems.*
Most useful: *The bibliography*

Institute for Safe Medication Practices www.ismp.org
Comments: *Offers products and services. On-line "Medication Safety Alert" identifies reported medication related safety problems. Message Board gives health care professionals the opportunity to post questions and receive advice from other health care providers who have had similar problems. Offers a medication safety self-assessment to both hospitals and community pharmacies. Many links to other sites are provided.*
Most useful: *Everything is a must see at this site. For community pharmacists, the community self-assessment may be the most useful tool for evaluating your current practice.*

Joint Commission on Accreditation of Healthcare Organizations www.jcaho.org
Comments: *Sentinel Event Alerts provide useful information for hospitals; however, these alerts deal with more than just medication related events. These alerts identify underlying causes and suggest steps for prevention.*
Most useful: *Hospitals will find the Sentinel Events Alert useful.*

California Institute for Health Systems Performance www.cihsp.org
Comments: *This is a medication safety collaborative (CISHP in partnership with California Healthcare Association). Provides a medication safety checklist (more applicable to hospital practice). Also provides a compendium of suggested practices, an 86-page document outlining strategies for improving patient safety. The compendium was developed to assist hospitals in preparing their medication error reduction plan (as required by SB1875) and covers prescribing, dispensing, administering, and monitoring medications. Also provides links to other sites.*
Most useful: *Community and hospital pharmacies will find the compendium of suggested practices useful.*

National Coordinating Council for Medication Error Reporting and Prevention. www.nccmerp.org
Comments: *Independent body comprised of 17 national organizations. This site provides the taxonomy for medication errors and is useful for the pharmacy implementing a new medication related events reporting system. Also provides council recommendations for various processes (e.g. bar coding).*
Most useful: *This site provides essential definitions for medication errors and sets up a severity ranking as well as possible breakdown points.*

VA National Center for Patient Safety www.patientsafety.gov
Comments: *Safety topics section provides straightforward clear explanations of commonly used QA tools (e.g. failure mode and effects analysis, root cause analysis). Has a "papers and publications" section that includes "TIPS" (Topics in Patient Safety) as well as a NCPS patient safety handbook.*
Most useful: *Both the Safety topics section and the TIPS newsletter have useful information.*

American Hospital Association www.aha.org
Comments: *Quality and Patient Safety section is very useful. Both the AHA initiatives and the successful safety practice sub-sections contain information on some of the most "pioneering and innovative efforts" going on in health care.*
Most useful: *The Successful Safety Practice section is a "must bookmark". Contains many pertinent articles relating to patient safety.*

US Pharmacopeia www.usp.org
Comments: *Drug information on over 11,000 generic and brand name drugs. Patient education information also available on this site. Practitioner reporting news includes examples of reported medication errors.*
Most useful: *The examples of reported medication errors serve as a great source of information to prevent similar errors from occurring.*

Pharmsafety.net www.pharmsafety.net
Comments: *Contains self-study materials that cover the practical applications of the interplay of cognitive, psychosocial factors and traditional pharmacy practices in reducing error, risk management, and promoting patient safety. Available to pharmacy personnel worldwide beginning in July, 2002 and can be downloaded free of charge. CE credit is available for US and Canadian pharmacists.*

Reporting Programs

FDA Medwatch www.fda.gov
Comments: *Voluntary reporting of serious adverse events, potential or actual medication product errors, and product quality issues. Can submit on-line, download form and fax, or call.*
Fax: 1-800-FDA-0178
Phone: 1-800 FDA-1088

USP Medication Errors Reporting Program www.usp.org/practrep/mer.htm
Comments: *Voluntary reporting system.*
Phone: 1-800-233-7767

MedMaRX (USP) www.medmarx.org
Comments: *Web-based reporting system. Fee to participate.*

JCAHO Sentinel Event Hotline www.jcaho.org
Comments: *Encourages hospitals to report sentinel events to the JCAHO as well as the root cause analysis performed in order to identify "lessons learned".*
Hotline Phone: 1-630-792-3700

Glossary

Adverse Drug Event (ADE): *An injury related to the use or non-use of a medication.*

Adverse Drug Reaction (ADR): *A subset of ADE. It includes any undesirable, unintended, or unexpected clinical manifestation associated with use of a medication.*

Adverse Event (AE): *An untoward, undesirable and usually unanticipated event, such as injury to or death of a patient.*

Continuous Quality Improvement (CQI): *A quality assurance program that is integrated into normal daily activities in order to obtain sufficient or improved quality on a continuous basis.*

Failure Mode Effects Analysis (FMEA): *A method for proactive assessment of a system or process that enables one to determine the location and mechanism of potential failures in advance.*

Medication Error: *any variation from a prescription or drug order not corrected prior to furnishing the drug to the patient (CCR, Title 16, section 1711).*

Outcome: *The result of the performance (or non-performance) of a function(s) or process(es).*

Potential ADE: *A hazardous situation that fails to cause injury by chance or because it is intercepted (caught) before the medication is administered to the patient. Sometimes referred to as "process errors" or "near misses."*

Process: *A goal-directed, interrelated series of actions, events, mechanisms, or steps.*

Quality Assurance: *A process used to ensure that a product or service meets appropriate or pre-determined standards.*

Root Cause Analysis (RCA): *A method for identifying the basic or causal factors that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event. A root cause analysis focuses primarily on systems and processes, not individual performance. Often initiated after an event has occurred (reactive)*

Risk Management: *Clinical and administrative activities to identify, evaluate, and reduce the risk of injury to patients, staff, visitors and the organization itself.*

Sentinel Event: *An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function.*

California Code of Regulations Tittle 16, Division 17
Quality Assurance Programs

1711. **(a)** Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

(b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in this section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

(c) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form. Unless the pharmacist has already been notified of a medication error by the prescriber or the patient, the pharmacist shall immediately communicate to the patient and the prescriber the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:

1. the date, location, and participants in the quality assurance review;
2. the pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);
3. the findings and determinations generated by the quality assurance review; and,
4. recommended changes to pharmacy policy, procedure, systems, or processes, if any.

The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.

(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created.

(g) The pharmacy's compliance with this section will be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.

(h) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.

This section shall become operative on January 14, 2002.

"Quality Assurance"

A Continuing Education Program for California Pharmacists

Universal Program #005-000-02-014-H04 • 3 Contact Hours (0.3 CEU)

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LEARNING OBJECTIVES

After reading the articles in this issue, you should be able to:

1. Describe at least five requirements of the pharmacy quality assurance regulation (Title 16 CCR, Section 1711).
2. List five items that must be documented whenever a medication error is investigated.
3. Describe three tools that are applicable to a pharmacy quality improvement program.
4. Describe three methods that are often used in continuous quality improvement.
5. Describe the differences between root cause analysis and failure mode and effects analysis and how each is applicable to continuous quality improvement.
6. Discuss three reasons why process errors (errors that do not reach the patient) should be tracked.
7. List three benefits derived from a national medication error-reporting program.
8. Describe seven best practices that would reduce the potential for medication errors.
9. Describe an effective strategy for dealing with patients after a medication error has been discovered.
10. List five steps consumers can take to protect themselves from a medication error.

DIRECTIONS FOR OBTAINING CE:

- Read the articles and take the test to receive three (3) hours of continuing education credit. Return the entire test page and include a self-addressed, stamped envelope. Please note that the passing grade is 70%. If necessary, one test will be readministered.
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25. _____

TEST QUESTIONS

1. Medication errors are the most common consumer complaint to the Board of Pharmacy.
   a) True
   b) False

2. California's quality assurance regulation defines a medication error as any variation from a prescription or drug order that is not corrected prior to furnishing the drug to the patient or patient's agent.
   a) True
   b) False

3. A prescription filled with the wrong medication that is corrected when counseling a patient is NOT a medication error.
   a) True
   b) False

4. Which one of the following is NOT required for a pharmacy to be in compliance with the pharmacy quality assurance regulation:
   a) The QA program must be documented in written policies and procedures
   b) Process errors that are corrected prior to furnishing the drug to the patient must be documented, but do not need to be formally reviewed.
   c) Discoveries resulting from a QA review of medication errors must be used to redesign systems and workflow processes to minimize the occurrence of medication errors.
   d) Investigations of medication errors must commence as soon as reasonably possible, but no later than 2 business days from the date of discovery.
   e) The pharmacists must notify both the patient and the physician when an error is discovered.

5. A record of quality assurance review must be immediately retrievable in the pharmacy for at least one year from the date it was created.
   a) True
   b) False

6. When a medication error is investigated, all of the following must be documented, except:
   a) The name and license number of the person who made the error.
   b) Date, location, and participants in the review.
   c) Pertinent data and other information related to the error being analyzed.
   d) Findings and determinations resulting from the QA review.
   e) Recommended changes to pharmacy policy, procedure, systems or processes, if any.

7. Simulation, a technique often used in aviation, is not helpful for improving safety in organizations where a hierarchy exists, such as in healthcare.
   a) True
   b) False

8. The advantages of monitoring process errors (errors that are corrected prior to reaching the patient) include all of the following, except:
   a) They occur in real time, when memories are still fresh.
   b) They signal that mindful thinking is emerging.
   c) They signal that mindless thinking is emerging
   d) They are precursors to actual medication errors
   e) None of the above.

9. Process errors are more likely to occur when the number of prescriptions being filled per hour increases.
   a) True
   b) False

10. A root cause analysis (RCA) will enable members of the pharmacy team to anticipate potential sources of medication errors prior to an error occurring.
    a) True
    b) False

11. A cause and effect (fishbone) diagram is one tool that is often used to enable members of a pharmacy team to visualize a root cause analysis (RCA).
    a) True
    b) False

12. Failure mode and effects analysis (FMEA) is considered a proactive quality improvement process because it uses inductive logic.
    a) True
    b) False

13. Failure mode and effects analysis (FMEA) enables members of the pharmacy team to visualize the underlying factors contributing to a medication error.
    a) True
    b) False

14. FMEA is very useful for evaluating complex systems where human beings are the only component in the system
    a) True
    b) False

15. Research has consistently shown that for every ____ process errors, one mistake will get past normal verification processes.
    a) 2
    b) 6
    c) 10
    d) 30
    e) 100

16. Report of a medication error to the USP's Medication Error Reporting Program may only be submitted on-line.
    a) True
    b) False

17. Which of the following benefits are derived from a national medication error-reporting program?
    a) Identification of problem-prone and high risk areas
    b) Adverse drug reaction reporting
    c) Proactive risk assessment
    d) Identification of "better practices"
    e) Choices a, b, and d above
    f) Choices a, c, and d above

18. Pharmacists practicing in any practice setting may spontaneously report medication errors to USP's Medication Error Reporting Program.
    a) True
    b) False

19. Consumers should routinely ask which of the following questions of their health care providers:
    a) What is the name of my medication and what is it supposed to do?
    b) What do I do if I forget to take my medication?
    c) Are there any side effects and what should I do if they occur?
    d) Is there any written information available about this medication?
    e) All of the above

20. Records of peer review activities relating to a medication error are protected from discovery and use in a lawsuit in California.
    a) True
    b) False

21. Which of the following practices does NOT help prevent medication errors:
    a) Identifying the person involved and disciplining that person.
    b) Filling the prescription from the hard copy rather than the label.
    c) Returning stock bottles of fast movers to the shelf in a timely manner.
    d) Opening the container and pouring a tablet or capsule in the lid to "show and tell" when counseling a patient.
    e) All of the above help prevent medication errors.

22. Good customer relations, honest communication, and a timely and caring response are effective strategies for dealing with patients after an error has occurred.
    a) True
    b) False

23. Computer order entry systems are one fail-proof way to reduce medication errors.
    a) True
    b) False

24. Many effective CQI programs are similar, in that they contain the following components:
    a) They engage everyone who participates in the work flow process.
    b) They foster reporting of errors with a non-punitive environment.
    c) They focus on systems-improvements and not individuals.
    d) Outcomes of process changes are studied and use for further improvements.
    e) All of the above.

HEALTH NOTES
Quality Assurance

Preventing Medication Errors

This issue of HEALTH NOTES is a collaborative effort of the California State Board of Pharmacy and the School of Pharmacy, University of California, San Francisco

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The Center for Consumer Self Care is an emerging collaborative center whose mission is to ensure optimal and responsible use of medication and dietary supplements by individuals and the public at large. The Center will accomplish its mission through the following program cores: Consumer Education, Research, Professional Education and Public Policy.

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